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dent of drugs and vaccines, in which asymptomatic infection and symbiosis are far more common than overt disease:

> It is barely recognized, but nevertheless true, that animals and plants, as well as men, can live peacefully with their most notorious microbial enemies. The world is obsessed by the fact that poliomyelitis can kill and maim several thousand unfortunate victims every year. But more extraordinary is the fact that millions upon millions of young people become infected by polio viruses, yet suffer no harm from the infection. The dramatic episodes of conflict between men and microbes are what strike the mind. What is less readily apprehended is the more common fact that infection can occur without producing disease.[4]

The principal evidence that the vaccines are effective actually dates from the more recent period, during which time the dreaded polio epidemics of the 1940s and 1950s have never reappeared in the developed countries, and measles, mumps, and rubella, which even a generation ago were among the commonest diseases of childhood, have become far less prevalent, at least in their classic acute forms, since the triple MMR vaccine was introduced into common use.

Yet how the vaccines actually accomplish these changes is not nearly as well understood as most people like to think it is. The disturbing possibility that they act in some other way than by producing a genuine immunity is suggested by the fact that the diseases in question have continued to break out even in highly immunized populations, and that in such cases the observed differences in incidence and severity between immunized and unimmunized persons have tended to be far less dramatic than expected, and in some cases not measurably significant at all.

In a recent British outbreak of whooping cough, for example, even fully immunized children contracted the disease in fairly large numbers, and the rates of serious complications and death were reduced only slightly.[5] In another recent outbreak of pertussis, 46 of the 85 fully immunized children studied eventually contracted the disease.[6]

In 1977, 344 new cases of measles were reported on the campus of UCLA in a population that was supposedly 91 percent immune, according to careful serological testing.[7] Another 20 cases of measles were reported in the Pecos, New Mexico, area within a period of a few months in 1981, and 75 percent of them had been fully immunized, some

of them quite recently.[8] A survey of sixth-graders in a well-immunized urban community revealed that about 15 percent of this age group are still susceptible to rubella, a figure essentially identical with that of the prevaccine era.[9]

Finally, although the overall incidence of typical acute measles in the U.S. has dropped sharply from about 400,000 cases annually in the early 1960s to about 30,000 cases by 1974–76, the death rate remained exactly the same;[10] and, with the peak incidence now occurring in adolescents and young adults, the risk of pneumonia and demonstrable liver abnormalities has actually increased substantially, according to one recent study, to well over 3 percent and 20 percent, respectively.[11]

The simplest way to explain these discrepancies would be to postulate that the vaccines confer only partial or temporary immunity, which sounds reasonable enough given the fact that they are either live viruses rendered less virulent by serial passage in tissue culture, or bacteria or bacterial proteins that have been killed or denatured by heat, such that they can still elicit an antibody response but no longer initiate the full-blown disease.

Because the vaccine is a "trick," in the sense that it simulates the true or natural immune response developed in the course of recovering from the actual disease, it is certainly realistic to expect that such artificial immunity will in fact "wear off" quite easily, and even require additional "booster" doses at regular intervals throughout life to maintain peak effectiveness.

Such an explanation would be disturbing enough for most people. Indeed, the basic fallacy inherent in it is painfully evident in the fact that there is no way to know how long this partial or temporary immunity will last in any given individual, or how often it will need to be restimulated, because the answers to these questions clearly depend on precisely the same individual variables that would have determined whether or how severely the same person, unvaccinated, would have contracted the disease in the first place.

In any case, a number of other observations suggests equally strongly that this simple explanation cannot be the correct one. In the first place, a number of investigators have shown that when a person vaccinated against the measles, for example, again becomes susceptible to it, even repeated booster doses will have little or no effect.[12]

In the second place, the vaccines do not act merely by producing pale or mild copies of the original disease; all of them also commonly produce

a variety of symptoms of their own. Moreoever, in some cases, these illnesses may be considerably more serious than the original disease, involving deeper structures, more vital organs, and less of a tendency to resolve spontaneously. Even more worrisome is the fact that they are almost always more difficult to recognize.

Thus, in a recent outbreak of mumps in supposedly immune schoolchildren, several developed atypical symptoms, such as anorexia, vomiting, and erythematous rashes, without any parotid involvement, and the diagnosis required extensive serological testing to rule out other concurrent disease.[13] The syndrome of "atypical measles" can be equally difficult to diagnose, even when it is thought of,[14] which suggests that is is often overlooked entirely. In some cases, atypical measles can be much more severe than the regular kind, with pneumonia, petechiae, edema, and severe pain,[15] and likewise can often go unsuspected.

In any case, it seems virtually certain that other vaccine-related syndromes will be described and identified, if only we take the trouble to look for them, and that the ones we are aware of so far represent only a very small part of the problem. But even these few make it less and less plausible to assume that the vaccines produce a normal, healthy immunity that lasts for some time but then *wears off*, leaving the patient miraculously unharmed and unaffected by the experience.

2. *Some Personal Experiences with Vaccine-Related Illness*

I would like now to present a few of my own vaccine cases, both to give a sense of their variety and chronicity, and to show how difficult it can be to trace them, and also to begin to address the crucial question that is too seldom even asked, namely, how the vaccines actually *work*, i.e., what effects they do in fact produce in the human body.

My first case was that of an eight-month-old girl with recurrent fevers of unknown origin. I first saw her in January of 1977, a few weeks after her third such episode. These were brief, lasting 48 hours at most, but very intense, with the fever typically reaching 105°F. During the second episode, she was hospitalized for diagnostic evaluation, but her pediatrician found nothing out of the ordinary. Apart from these episodes, the child felt quite well, and appeared to be growing and developing normally.

I could get no further information from the mother, except for the fact that the episodes had occurred almost exactly one month apart; and, upon

consulting her calendar, we learned that the first episode had come exactly one month after the last of her DPT injections, which had also been given at monthly intervals. At this point, the mother remembered that the child had had similar febrile episodes immediately after each injection, but that she had been instructed to ignore them, inasmuch as they are "common reactions" to the vaccine. I therefore gave the child a single *oral* dose of dilute homeopathic DPT vaccine; and I am happy to report that the child has remained well since, with no further episodes of any kind.

This case illustrates how homeopathic remedies prepared from vaccines can be used for *diagnosis* as well as treatment of vaccine-related illnesses, which, no matter how strongly they are suspected, might otherwise be almost impossible to substantiate.

Secondly, because fever is the commonest known complication of the pertussis vaccine, and inasmuch as the child seemed quite well between the attacks, her response to the vaccine appeared to be a relatively strong and healthy one, disturbing because of its recurrence and periodicity, but in any case relatively simple to cure, as indeed it proved to be. But one cannot help wondering what happens to the vaccine in those tens of millions of children who show no obvious reponse to it at all.

Since that time, I have seen numerous cases of children with recurrent fevers of unknown origin, associated with a variety of other chronic complaints, chiefly irritability, temper tantrums, and increased susceptibility to colds, tonsillitis, and ear infections, which were similarly traceable to the pertussis vaccine, and which responded successfully to treatment with the homeopathic DPT nosode. Indeed, I would have to say, on the basis of that experience, that the DPT vaccine is probably one of the major causes of recurrent fevers of unknown origin in small children today.

My second case was that of a 9½-month-old girl, who presented acutely with a fever of 105° F., and very few other symptoms. Like the first, this child had had two similar episodes previously, but at irregular intervals; and the parents, who felt ambivalent about vaccinations in general, had given her only one dose of the DPT vaccine so far, although the first episode occurred a few weeks afterwards.

I first saw the child in June of 1978. The fever remained high and unremitting for 48 hours, despite the usual acute remedies and supportive measures. A CBC revealed a white count of 32,100 per mm.3, with 43 percent lymphocytes, 11 percent monocytes, 25 percent neutrophilis

(many with toxic granulations), and 1 percent metamyelocytes and other immature forms. When I asked a pediatrician about these findings, "pertussis" was his immediate reply. After a single oral dose of homeopathic DPT vaccine, the fever came down abruptly within a few hours, and the child has remained well since.

This case was disturbing mainly because of the hematological abnormalities, which were in the leukemoid range, together with the absence of any cough or distinctive respiratory symptoms, which suggested that introducing the vaccine directly into the blood may actually promote deeper or more systematic pathology than allowing the pertussis organism to set up typical symptoms of local inflammation at the normal portal of entry.

The third case was a five-year-old boy with chronic lymphocytic leukemia, whom I happened to see in August of 1978, while visiting an old friend and teacher, a family physician with over 40 years' experience. Well out of earshot of either the boy or his parents, he told me that the leukemia had first appeared following a DPT vaccination, and that, although he had treated the child successfully with natural remedies on two previous occasions, with shrinking of the liver and spleen to approximately normal size, and dramatic improvement in the blood picture, full relapse had occurred soon after each successive DPT booster.

The idea that vaccinations might also be implicated in some cases of childhood leukemia was shocking enough in itself, but it also completed the line of reasoning opened up by the previous case. For leukemia is a cancerous process of the blood and the blood-forming organs, the liver, the spleen, the lymph nodes, and the bone marrow, which are also the basic anatomical units of the immune system. Insofar as the vaccines are capable of producing serious complications at all, the blood and the immune organs would certainly be the logical place to begin looking for them.

But perhaps even more shocking to me is the fact that the boy's own physician dared not communicate his suspicion of vaccine-related illness to the parents, let alone to the general public. It was this case that convinced me, once and for all, of the need for serious, public discussion of our collected experiences with vaccine-related illness, precisely because rigorous experimental proof will require years of investigation and a firm public commitment that has not even been made yet.

I will now present two cases from my limited experience with MMR vaccine.

> In December of 1980 I saw a three-year-old boy with a four-week history of loss of appetite, stomachaches, indigestion, and swollen glands. The stomach pains were quite severe, and often accompanied by belching, flatulence, and explosive diarrhea. The nose was also congested, and the lower eyelids were quite red. The mother also reported some unusual behavior changes, such as extreme untidiness, "wild" and "noisy" playing, and waking at 2 A.M. to get into bed with the parents.
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> The physical examination was unremarkable except for some large, tender left posterior auricular and suboccipital nodes, and marked enlargement of the tonsils. I then learned that the child had received the MMR vaccine in October, about two weeks before the onset of symptoms, with no apparent reaction to it at the time. I gave the child a single dose of the homeopathic rubella vaccine, and the symptoms promptly disappeared within 48 hours.
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> In April 1981, the parents brought him back for a slight fever, and another three-week history of intermittent pain in and behind the right ear, stuffy nose, etc. On examination, the whole right side of the face appeared to be swollen, especially the cheek and the angle of the jaw. The right eye was red and infected. He responded well to acute homeopathic remedies and has remained well since.

This boy was typical of my rubella vaccine cases. At an interval of a few weeks after the MMR vaccine, which is about the same as the normal incubation period of rubella, a rather nondescript illness develops, which becomes subacute and rather more severe than rubella in the same age group, with, e.g., abdominal or joint pains and marked adenopathy, but no rash. Usually the diagnosis is suspected because of the characteristic posterior auricular and suboccipital nodes, and confirmed by a favorable response to the homeopathic rubella nosode.

As I read over this case, I am struck by the possibility that his second illness, and especially the parotid enlargement, may have represented continuing activity of the mumps component of the vaccine, inasmuch as I did not have the triple MMR nosode, but only those derived from the individual components. We must therefore also consider the probability that a variety of "mixed" or composite syndromes may occur, representing the patient's responses to two or all three of the vaccine components, either simultaneously or over time.

In April of 1981 I first saw a four-year-old boy for bilateral chronic enlargement of the posterior auricular nodes, which were also occasionally tender. The mother had noticed the swelling for about one year, during which time he had become more susceptible to various upper respiratory infections, none of them especially severe. The mother had also noticed recurrent parotid swelling at irregular intervals over the same time period, which began shortly after the MMR vaccine was given at the age of three.

At the time of the first visit, the child was not ill, and because the mother was about two months pregnant at the time, I elected to observe the child and do nothing if possible until the pregnancy was over. He did develop a mild laryngitis in the last trimester, which responded well to bed rest and simple homeopathic remedies.

In April of 1982, he came down with acute bronchitis. I noticed that the posterior auricular nodes were once again swollen and tender and decided to give him the homeopathic rubella nosode at that point. The cough promptly subsided, and the nodes regressed in size and were no longer tender. Two weeks later, however, he returned with a noticeably hard, tender swelling on the outside of the right cheek, near the angle of the jaw, and some pain on chewing or opening the mouth. A single dose of the homeopathic mumps nosode was given, and the child has been well since.

In this case also, we see the subacute pattern of the disease, with a strong tendency to chronicity and increased susceptibility to weaker, low-grade responses, in contrast to the vigorous, acute responses typically associated with diseases like the measles and the mumps when acquired naturally.

3. *How Do the Vaccines Work?*

It is dangerously misleading, and, indeed, the exact opposite of the truth to claim that a vaccine makes us "immune" or *protects* us against an acute disease, if in fact it only drives the disease deeper into the interior and causes us to harbor it *chronically*, with the result that our responses to it become progressively weaker, and show less and less tendency to heal or resolve themselves spontaneously.

What I propose, then, is simply to investigate as thoroughly and objectively as we can how the vaccines actually *work* inside the human body, and to begin by paying attention to the implications of what we already know. In particular, I would like to consider in detail the process

of falling ill with and recovering from a typical acute disease, such as the measles, in contrast with what we can observe following the administration of the measles vaccine.

We all know that measles is primarily a virus of the respiratory tract, both because it is inhaled by susceptible persons upon contact with infected droplets in the air, and because these droplets are produced by the coughing and sneezing of a person with the disease.

Once inhaled by a susceptible person, the measles virus then undergoes a long period of silent multiplication, first in the tonsils, adenoids, and accessory lymphoid tissues of the nasopharynx; later in the regional lymph nodes of the head and neck; and, eventually, several days later, it passes into the blood and enters the spleen, the liver, the thymus, and the bone marrow, the visceral organs of the immune system.[16] Throughout this incubation period, which lasts from 10 to 14 days, the patient usually feels quite well and experiences few or no symptoms.[17]

By the time that the first symptoms of measles appear, circulating antibodies are already detectable in the blood, and the height of the symptomatology coincides with the peak of the antibody response.[18] In other words, the "illness" is simply the definitive effort of the immune system to clear the virus from the blood. Equally noteworthy is the fact that the virus is eliminated by sneezing and coughing, i.e., via the same route through which it entered in the first place.

It is evident that the process of *mounting* an acute illness like the measles, no less than recovering from it, involves a general mobilization of the entire immune system, including inflammation of the previously sensitized tissues at the portal of entry, activation of leukocytes and macrophages, liberation of the serum complement system, and a host of other mechanisms, of which the production of circulating antibody is only one, and by no means the most important.

Such a splendid outpouring leaves little doubt that such illnesses are in fact the decisive experiences in the normal physiological maturation of the immune system as a whole in the life of a healthy child. For not only will the child who recovers from the measles never again be susceptible to it;[19] such an experience also cannot fail to prepare the individual to respond even more promptly and effectively to any infections he may acquire in the future. The ability to mount a vigorous acute response to organisms of this type must therefore be reckoned among the most fundamental requirements of general health and well-being.

In contrast, when an artificially attenuated virus such as measles is

injected directly into the blood, bypassing the normal portal of entry, at most a brief inflammatory reaction may be noted at the injection site, or in the regional lymph nodes, but there is no "incubation period" of local contact at the normal portal of entry, and consequently very little possibility of eliminating the virus via the same route.

Even more important is the fact that the virus has been artificially "attenuated," so that it will no longer initiate a generalized inflammatory response, or indeed any of the nonspecific defense mechanisms that help us to respond to infection generally. By "tricking" the body in this fashion, we have accomplished what the entire immune system seems to have evolved in order to prevent: We have placed the virus directly into the blood, and given it free and immediate access to the major immune organs, without any obvious way of getting rid of it.

The result is, indeed, the production of circulating antibodies against the virus; but the antibody response now occurs as an isolated technical feat, without any generalized inflammatory response, or any noticeable improvement in the general health of the organism. Exactly the opposite, in fact: The price that we have to pay for those antibodies is the persistence of virus elements in the blood for prolonged periods of time, perhaps permanently, which in turn presupposes a systematic weakening of our ability to mount an effective response not only to measles, but also to other acute infections as well.

Far from producing a genuine immunity, then, the vaccines may act by actually interfering with or *suppressing* the immune response as a whole, in much the same way that radiation, chemotherapy, and corticosteroids and other anti-inflammatory drugs do. Artificial immunization focuses on *antibody production*, a single aspect of the immune process, and disarticulates it and allows it to stand for the whole, in much the same way as chemical suppression of an elevated blood pressure is accepted as a valid substitute for a genuine *cure* of the patient whose blood pressure has risen. Worst of all, by making it difficult or impossible to mount a vigorous, acute response to infection, artificial immunization substitutes for it a much weaker, *chronic* response with little or no tendency to heal itself spontaneously.

Moreover, adequate models already exist for predicting and explaining what sorts of chronic disease are likely to result from the chronic, long-term persistence of viruses and other foreign proteins within the cells of the immune system. It has long been known that live viruses, for example, are capable of surviving or remaining latent within the host

cells for years, without continually provoking acute disease. They do so simply by attaching their own genetic material as an extra particle or "episome" to the genome of the host cell, and replicating along with it, which allows the host cell to continue its own normal funtions for the most part, but imposes on it additional instructions for the synthesis of viral proteins.[20]

Latent viruses of this type have already been implicated in three distinct types of chronic disease, namely (1) *recurrent or episodic acute diseases* such as herpes, shingles, warts, etc.[21]; (2) *"slow-virus" diseases*, i.e., subacute or chronic, progressive, often fatal conditions, such as kuru, Creutzfeldt-Jakob disease, subacute sclerosing panencephalitis (SSPE), AIDS, and possibly Guillain-Barre syndrome[22]; and (3) *tumors*, both benign and malignant.[23]

In any case, the latent virus survives as a clearly "foreign" element within the cell, which means that the immune system must continue to try to make antibodies against it, insofar as it can still respond to it at all. Because the virus is now permanently incorporated within the genetic material of the cell, these antibodies will now have to be directed against the cell itself.

The persistence of live viruses or other foreign antigens within the cells of the host therefore cannot fail to provoke *auto-immune* phenomena, because destroying the infected cells is now the only possible way that this constant antigenic challenge can be removed from the body. Since routine vaccination introduces live viruses and other highly antigenic material into the blood of virtually every living person, it is difficult to escape the conclusion that a significant harvest of auto-immune diseases will automatically result.

Sir Macfarlane Burnet has observed that the components of the immune system all function as if they were collectively designed to help the organism to discriminate "self" from "nonself," i.e., to help us to recognize and tolerate our own cells, and to identify and eliminate foreign or extraneous substances as completely as possible.[24] This concept is exemplified not only by the acute response to infection, but also by the rejection of transplanted tissues, or "homografts," both of which result in the complete and permanent removal of the offending substance from the body.

If Burnet is correct, then latent viruses, auto-immune phenomena, and cancer would seem to represent different aspects of the same basic dilemma, which the immune system can neither escape nor resolve. For

all of them presuppose a certain degree of *chronic immune failure*, a state in which it becomes difficult or impossible for the body either to recognize its own cells as unambiguously its own, or to eliminate its parasites as unequivocally foreign.

In the case of the attenuated measles virus, it is not difficult to imagine that introducing it directly into the blood would continue to provoke an antibody response for a considerable period of time, which is doubtless the whole point of giving the vaccine; but that eventually, as the virus succeeded in attaining a state of latency within the cell, the antibody response would wane, both because circulating antibodies cannot normally cross the cell membrane, and also because they are powerful immunosuppressive agents in their own right.[25]

The effect of circulating antibody will thereafter be mainly to keep the virus *within* the cell, i.e., to continue to prevent any acute inflammatory response, until eventually, perhaps under circumstances of accumulated stress or emergency, this precarious balance breaks down, antibodies begin to be produced in large quantities against the cells themselves, and frank auto-immune phenomena of necrosis and tissue destruction supervene. Latent viruses, in this sense, are like biological "time bombs," set to explode at an indeterminate time in the future.[26]

Auto-immune diseases have always seemed obscure, aberrant, and bizarre, because it is not intuitively obvious why the body should suddenly begin to attack and destroy its own tissues. They make a lot more sense, and, indeed, must be reckoned as "healthy," if destroying the chronically infected cells is the only possible way of eliminating an even more serious threat to life, namely, the persistence of the foreign antigenic challenge within the cells of the host.

Tumor formation could then be understood as simply a more advanced stage of chronic immune failure, according to the same model. For, as long as the host is subjected to enormous and unremitting pressure to make antibodies against itself, that response will automatically tend to become less and less effective.

Eventually, under stress of this magnitude, the auto-immune mechanism could easily break down to the point that the chronically infected and genetically transformed cells, no longer clearly "self" or "nonself," begin to free themselves from the normal restraints of "histocompatibility" within the architecture of the surrounding cells, and begin to multiply autonomously at their expense.

A tumor could then be described as "benign" insofar as the break-

down of histocompatibility remains strictly localized to the tissue of [illegible] and "malignant" [illegible] to spread to other cell types, tissues, and organs, even in more remote areas. Malignancy might simply [illegible] into a more [illegible] with less [illegible]

If what I am saying turns out to be true, then what we have done by artificial immunizations is essentially to trade off our acute, epidemic disease of the past century for the weaker and far less curable chronic diseases of the present, with their amortizable suffering and disability. In doing so, we have also opened up limitless evolutionary possibilities for the future of ongoing *in vivo* genetic recombination within the cells of the race.

4. *The Individual Vaccines Reconsidered*

I want next to consider each of the vaccines on an individual basis, in relation to the infectious diseases from which they are derived.

The MMR is composed of attenuated live measles, mumps, and rubella viruses administered in a single intramuscular injection at about 15 months of age. Subsequent reimmunization is no longer recommended, except for young women of childbearing age, in whom the risk of congenital rubella syndrome (CRS) is thought to warrant it, even though the effectiveness of reimmunization is questionable at best.

Prior to the vaccine era, measles, mumps, and rubella were reckoned among the "routine childhood diseases," which most schoolchildren contracted before the age of puberty, and from which nearly all recovered with permanent, lifelong immunity, and no complications or sequelae.

But they were not always so harmless. Measles, in particular, can be a devastating disease when a population encounters it for the first time. Its importation from Spain, for instance, undoubtedly contributed to Cortez' conquest of the great Aztec Empire: Whole villages were carried off by epidemics of measles and smallpox, leaving only a small remnant of cowed, superstitious warriors to face the bearded *conquistadores* from across the sea.[27] In more recent outbreaks among isolated, primitive people, the case fatality rate from measles averaged 20 to 30 percent.[28]

In these so-called "virgin-soil" epidemics, not only measles but also polio and many other similar diseases take their highest toll of death and

serious complications among adolescents and young adults, healthy and vigorous people in the prime of life, and leave relatively unharmed the group of school-age children before the age of puberty.[29]

This means that the evolution of a disease such as measles from a dreaded killer to an ordinary disease of childhood presupposes the development of nonspecific or "herd" immunity in young children, such that, when they are finally exposed to the disease, it activates defense mechanisms already prepared and in place, resulting in the long incubation period and the usually benign, self-limited course described above.

Under these circumstances, the rationale for wanting to vaccinate young children against measles is limited to the fact that a very small number of deaths and serious complications have continued to occur, chiefly pneumonia, encephalitis, and the rare but dreaded subacute sclerosing panencephalitis (SSPE), a slow-virus disease with a reported incidence of 1 per 100,000 cases.[30] Pneumonia, by far the commonest complication, is usually benign and self-limited, even without treatment[31]; and, even in those rare cases in which bacterial pneumonia supervenes, adequate treatment is currently available.

By all accounts, then, the death rate from wild-type measles is very low, the incidence of serious sequelae is insignificant, and the general benefit to the child who recovers from the disease and to his contacts and descendants, is very great. Consequently, even if the measles vaccine could be shown to reduce the risk of death or serious complications from the disease, it still could not justify the high probability of auto-immune diseases, cancer, and whatever else may result from the propagation of latent measles virus in human tissue culture for life.

Ironically, what the measles vaccine certainly has done is to reverse the historical or evolutionary process to the extent that measles is once again a disease of adolescents and young adults,[32] with a correspondingly higher incidence of pneumonia and other complications and a general tendency to be a more serious and disabling disease than it usually is in younger children.

As for the claim that the vaccine has helped to eliminate measles encephalitis, I myself, in my own relatively small general practice, have already seen two children with major seizure disorders which the parents clearly ascribed to the measles vaccine, although they would never have been able to prove the connection in a court of law, and never considered the possibility of compensation.

Such cases therefore never make the official statistics, and are accordingly omitted from conventional surveys of the problem. Merely injecting the virus into the blood would naturally favor a higher incidence of deep or visceral complications affecting the lungs, liver, and brain, for which the measles virus has a known affinity.

The case for immunizing against mumps and rubella seems *a fortiori* even more tenuous, for exactly the same reasons. Mumps is also essentially a benign, self-limited disease in children before the age of puberty, and recovery from a single attack confers lifelong immunity. The principal complication is meningoencephalitis, mild or subclinical forms of which are relatively common, although the death rate is extremely low,[33] and sequelae are rare.

The mumps vaccine is prepared and administered in much the same way as the measles, usually in the same injection; and the dangers associated with it are likewise comparable. Again, like the measles, mumps is fast becoming a disease of adolescents and young adults,[34] age groups which do not tolerate the disease as well. The chief complication is acute epididymo-orchitis, which occurs in 30 to 40 percent of the males affected past the age of puberty, and usually results in atrophy of the testicle on the affected side[35]; but it also shows a strong tendency to attack the ovary and the pancreas.

For all of these reasons, the greatest favor we could do for our children would be to expose them all to the measles and mumps when they are young, which would not only protect them against contracting more serious forms of these diseases when they grow older, but would also greatly assist in their immunological maturation with minimal risk. I need hardly add that this is very close to the actual evolution of these diseases before the MMR vaccine was introduced.

The same discrepancy is evident in the case of rubella, or "German measles," which in young children is a disease so mild that it frequently escapes detection,[36] but in older children and adults not infrequently produces arthritis, purpura, and other severe, systemic signs.[37] The main impetus for the development of the vaccine was certainly the recognition of the congenital rubella syndrome (CRS) resulting from damage to the developing embryo in utero during the first trimester of pregnancy,[38] and the relatively high incidence of CRS traceable to the rubella outbreak of 1964.

But here again, we have an almost entirely benign, self-limited disease transformed by the vaccine into a considerably less benign disease of

adolescents and young adults of reproductive age, which is, ironically, the group that most needs to be protected against it. Moreover, as with measles and mumps, the simplest and most effective way to prevent CRS would be to expose everybody to rubella in elementary school; reinfection does sometimes occur after recovery from rubella, but much less commonly than after vaccination.[39]

The equation looks somewhat different for the diphtheria and tetanus vaccines. First of all, both diphtheria and tetanus are serious, sometimes fatal diseases, even under the best of treament; this is especially true of tetanus, which still carries a mortality of anywhere from 20 to 50 percent.

Furthermore, these vaccines are not made from living diphtheria and tetanus organisms, but only from certain "toxins" elaborated by them; these poisonous substances are still highly antigenic even after being inactivated by heat. Diphtheria and tetanus "toxoids" therefore do not protect against infection per se, but only against the systemic action of the original poisons in the absence of which both infections are of minor importance clinically.

Consequently, it is easy to understand why parents might want their children protected against diphtheria and tetanus, if safe and effective protection were available. Moreover, both vaccines have been in use for a long time, and the reported incidence of serious problems has remained very low, so that there has never been much public outcry against them.

On the other hand, both diseases are quite readily controlled by simple sanitary measures and careful attention to wound hygiene; and, in any case, both have been steadily disappearing from the developing countries, since long before the vaccines were introduced.

Diphtheria now occurs sporadically in the United States, often in areas with significant reservoirs of unvaccinated children. But the claim that the vaccine is "protective" is once again belied by the fact that, when the disease does break out, the supposedly "susceptible" children are in fact no more likely to develop clinical diphtheria than their fully immunized contacts. In a 1969 outbreak in Chicago, for example, the Board of Health reported that 25 percent of the cases had been fully immunized and that another 12 percent had received one or more doses of the vaccine and showed serological evidence of full immunity, whereas 18 percent had been partly immunized according to the same criteria.[40]

So, once again, we are faced with the probability that what the diphtheria toxoid has produced is not a genuine immunity to diphtheria at all, but rather some sort of chronic immune *reaction* to it, by harboring highly antigenic residues somewhere within the cells of the

immune system, presumably with long-term suppressive effects on the immune mechanism generally.

This suspicion is further aggravated by the fact that all of the DPT vaccines are alum-precipitated and preserved with thimerosal, an organomercury derivative, to prevent them from being metabolized too rapidly, so that the antigenic challenge will continue for as long as possible. The fact is that we do not know and have never even attempted to discover what actually becomes of these foreign substances once they are inside the human body.

Exactly the same problems complicate the record of the tetanus vaccine, which almost certainly has had at least some impact in reducing the incidence of tetanus in its classic acute form, yet presumably also survives for years or even decades as a potent foreign antigen within the body, with long-term effects on the immune system and elsewhere that are literally incalculable.

"Whooping cough," much like diphtheria and tetanus, began to decline as a serious epidemiological threat long before the vaccine was introduced. Moreover, the vaccine has not been particularly effective, even according to its proponents; and the incidence of known side effects is disturbingly high.

The power of the pertussis vaccine to damage the central nervous system, for example, has received growing attention since Stewart and his colleagues reported an alarmingly high incidence of encephalopathy and severe convulsive disorders in British children that were traceable to the vaccine.[41] My own cases, a few of which were reported above, suggest that hematological disturbances may be even more prevalent, and that, in any case, the *known* complications almost certainly represent a small fraction of the total.

In any case, the pertussis vaccine has become controversial even in the United States, where medical opinion has remained almost unanimously in favor of immunizations generally, and several countries, such as West Germany, have discontinued routine pertussis vaccination entirely.[42]

Pertussis is also extremely variable clinically, ranging in severity from asymptomatic, mild, or inapparent infections, which are quite common actually, to very rare cases in young infants less than five months of age, in which the mortality is said to reach 40 percent.[43] Indeed, the disease is rarely fatal or even that serious in children over a year old, and antibiotics have very little to do with the outcome.[41]

A good deal of the pressure to immunize at the present time thus seems to be attributable to the higher death rate in very young infants,

which has led to the terrifying practice of giving this most clearly dangerous of the vaccines to infants at two months of age, when their mother's milk would normally have protected them from all infection about as well as it can ever be done,[45] and the effect on the still developing blood and nervous system could be catastrophic.

For all of these reasons, the practice of routine pertussis immunization should be discontinued as quickly as possible and more studies done to assess and compensate the damage that it has already done.

Poliomyelitis and the polio vaccines present an entirely different situation. The standard Sabin vaccine is trivalent, consisting of attenuated, live polioviruses of each of the three strains associated with poliomyelitis; but it is administered orally, in much the same way as the infection is acquired in nature. The oral or noninjectable route, which leaves the recipient free to develop a natural immunity at the normal portal of entry, i.e., the GI tract, would therefore appear to represent a considerable safety factor.

On the other hand, the wild-type poliovirus produces no symptoms whatsoever in over 90 percent of the people who contact it, even under epidemic conditions[46]; and, of those people who do come down with recognizable clinical disease, perhaps only 1 or 2 percent ever progress to the full-blown neurological picture of "poliomyelitis," with its characteristic lesions in the anterior horn cells of the spinal cord or medulla oblongata.[47]

Poliomyelitis thus presupposes peculiar conditions of susceptibility in the host, even a specific *anatomical* susceptibility, since, even under epidemic conditions, the virulence of the poliovirus is so low, and the number of cases resulting in death or permanent disability was always remarkably small.[48]

Given the fact that the poliovirus was ubiquitous before the vaccine was introduced, and could be found routinely in samples of raw sewage wherever it was looked for,[49] it is evident that effective natural immunity to poliovirus was already as close to being universal as it can ever be, and a fortiori that no artificial substitute could ever equal or even approximate that result. Indeed, because the virulence of the poliovirus was so low to begin with, it is difficult to see what further attenuation of it could possibly accomplish, other than to abate as well the full vigor of the natural immune response to it.

For the fact remains that even the attenuated virus is still alive, and that the people who were anatomically susceptible to it before are still susceptible to it now. This means, of course, that at least *some* of these

same people will develop paralytic polio from the vaccine,[50] and that the others may still be harboring the virus in latent form, perhaps within those same cells.

The only obvious advantage of giving the vaccine, then, would be to introduce the population to the virus when they are still infants, and the virulence is normally lowest anyway[51]; and even this benefit could be more than offset by the danger of weakening the immune response, as we have seen. In any case, the whole matter is clearly one of enormous complexity, and illustrates only too well the hidden dangers and miscalculations that are inherent in the virtually irresistible attempt to beat nature at her own game, to eliminate a problem that cannot be eliminated, i.e., the susceptibility to disease itself.

So even in the case of the polio vaccine, which appears to be about as safe as any vaccine ever *can* be, the same fundamental dilemma remains. Perhaps the day will come when we can face the consequences of deliberately feeding live polioviruses to every living infant, and admit that we should have left well enough alone, and addressed ourselves to the art of healing the sick when we have to, rather than to the technology of eradicating the *possibility* of sickness, when we don't have to, and can't possibly succeed in any case.

5. *Vaccination and the Path of Medical Technology*

In conclusion, I want to go back to the beginning, to the essentially political aspects of vaccination, that oblige us all to reason and deliberate together about matters of common concern, and to reach a clear decision about how we choose to live. I have stated my own views regarding the safety and effectiveness of the vaccines, and I hope that others of differing views will do the same.

That is why I am deeply troubled by the atmosphere of fanaticism with which the vaccines are imposed on the public, and serious discussion of them is ignored or stifled by the medical authorities, as if the question had already been settled definitively and for all time. In the words of Sir Macfarlane Burnet:

> It is our pride that in a civilized country the only infectious diseases which anyone is likely to suffer are either trivial or easily cured by available drugs. The diseases that killed in the past have in one way or another been rendered impotent, and, in the process, general principles of control have been developed which should be applicable to any unexpected outbreak in the future.[52]

Quite apart from the truth of these claims, they exemplify the smugness and self-righteousness of a profession and a society that worships its own ability to manipulate and control the processes of nature itself. That is why, as Robert Mendelsohn has said, "We are quick to pull the trigger, but slow to examine the consequences of our actions."[53]

Indeed, one would have to say, *methodically* slow. In 1978, for example, the American Academy of Pediatrics, which had been charged by Congress with responsibility to formulate guidelines for federal compensation of "vaccination-related injuries," issued the following eligibility restrictions:

> 1. Compensation should be made available to any child or young person under the age of 18 years, or a contact of such person of any age, who suffers a major reaction to a vaccine mandated for school entry or continuation in his or her state of residence.
> 2. Such a reaction should have been previously recognized as a possible consequence of the vaccine given.
> 3. Such a reaction should have occurred no more than 30 days following the immunization.[54]

These restrictions would automatically exclude all of the chronic diseases, or indeed anything other than the very few adverse reactions that have so far been identified, which clearly represent only a tiny fraction of the problem.

Still less can either the government or the medical establishment be considered ignorant of the possibility that lurks in every parent's mind and heart, namely, that the vaccines cause cancer and other chronic diseases. Precisely that possibility was raised by Professor Robert Simpson of Rutgers in a 1976 seminar for science writers sponsored by the American Cancer Society:

> Immunization programs against flu, measles, mumps, polio, and so forth, may actually be seeding humans with RNA to form latent proviruses in cells throughout the body. These latent proviruses could be molecules in search of diseases; when activated, under proper conditions, they could cause a variety of diseases, including rheumatoid arthritis, multiple sclerosis, systemic lupus erythematosus, Parkinson's disease, and perhaps cancer.[55]

Unfortunately, this is the sort of warning that very few people are willing or able to hear at this point, least of all the American Cancer Society or the American Academy of Pediatrics. The fact is, as Dubos points out, that all of us still want to believe in the "miracle," regardless of the evidence:

> The faith in the magical power of drugs often blunts the critical senses, and comes close at times to a mass hysteria, involving scientists and laymen alike. Men want miracles as much today as in the past. If they do not join one of the newer cults, they satisfy this need by worshipping at the altar of modern science. This faith in the magical power of drugs is not new. It helped to give medicine the authority of a priesthood and to recreate the glamour of ancient mysteries.[56]

The idea of eradicating measles or polio has come to seem attractive to us simply because the power of medical science makes it seem technically *possible;* we worship every victory of technology over nature, just as the bullfight celebrates the triumph of human intelligence over the brute beast.

That is why we do not begrudge the drug companies their enormous profits, and gladly volunteer our own bodies and those of our children for their latest experiments. Vaccination is essentially a religious sacrament of our own participation in the miracle, a veritable auto-da-fe in the name of modern civilization itself.

Nobody in his right mind would seriously entertain the idea that if we could somehow eliminate, one by one, measles and polio and all the known diseases of mankind, we would be any the healthier for it, or that other even more serious diseases would not quickly take their places.

Still less would a rational being suppose that the illnesses from which he suffered were "entities" somehow separable from the patients who suffer them, and that, with the appropriate chemical or surgical sacrament, this separation can literally be carried out.

Yet these are precisely the "miracles" we are taught to believe in, and the idolatries to which we aspire. We prefer to forget the older and simpler truths, that the propensity or susceptibility to illness is deeply rooted in our biological nature and that the phenomena of disease are the expression of our own life energy, trying to overcome whatever it is trying to overcome, trying, in short to *heal itself.*

The myth that we can find technical solutions for all human ailments seems attractive at first, precisely because it bypasses the problem of

healing, which is a genuine miracle in the sense that it can always *fail* to occur. We are all genuinely at risk of illness and death at every moment; no amount of technology can change that. Yet the mission of technical medicine is precisely to try to change that: to stand at all times in the front lines against disease, and to attack and destroy it whenever and wherever it shows itself.

That is why, with all due respect, I cannot have faith in the miracles or accept the sacraments of Merck, Sharp, and Dohme and the Center for Disease Control. I prefer to stay with the miracle of life itself, which has given us illness and disease, but also the arts of medicine and healing, through which we can acknowledge and experience our pain and our vulnerability, and sometimes, with the grace of God and the help of our fellow men, an awareness of health and well-being that transcends all boundaries. That is *my* religion; and, while I would willingly share it, I would not *force* it on anyone.

Postscript on Immunizations: Directions for Future Research

In "Immunizations—A Dissenting View," my intention was simply to understand my own experience, to develop a coherent and plausible line of reasoning that could explain what I had read and felt and thought about, and what my patients were telling me.

The next step is to address the issue of *experimental verification*, to try to sketch out where and how we might look for valid, repeatable evidence for the efficacy, safety, and mode of action of the common vaccines.

As I reread the argument, I realized that even the more speculative ideas in it could in fact be tested quite easily with the standard research techniques now in common use. Because I myself have very little research training or experience, I am doubly curious why such tests were not carried out long ago.

A number of scholars have certainly *entertained* these ideas before, as I indicated in the text, and even considered them publicly. The only obstacle that I can see to taking them seriously is that they are "heretical," that it would be impossible even to take the time to study them without a "paradigm shift" of some magnitude.[57]

1. How Effective Are the Vaccines?

If the vaccines act by *suppressing* the ability of the organism to mount

an effective acute inflammatory response, then we can no longer accept a simple drop in the incidence of the acute disease as a measure of true immunity. I also argued that the mere presence of circulating antibody cannot suffice either, because the diseases in question do continue to break out, even in serologically highly "immune" populations.

What strikes me as a far more interesting and relevant measurement is the degree to which the vaccine "protects" against the acute disease when the latter actually does break out. This could be determined relatively easily by studying the incidence and morbidity of each disease in fully and partly immunized populations, as compared with those of their nonimmunized neighbors. Such a study would still have nothing to say about the possibility of immunosuppression. But it would at least give a truer perspective on the ability of the vaccines to do what their proponents seem to *want* them to do.

I cannot resist pointing out that such research obviously requires a sizable cohort of unimmunized people, which is now being provided by those parents who have refused to immunize their children, despite the concerted efforts of the medical and public health authorities to intimidate and punish them. The same result could of course be achieved much more efficiently by simply making the vaccines *optional*, as they are in West Germany, Sweden, the United Kingdom, and some other places, which would allow the experimental and control groups to select themselves. Our frantic efforts to secure 100 percent compliance with the present mandatory program evidently succeeds only in making such studies impossible.

A closely related type of study would be to measure the effectiveness of *reimmunization* at varying intervals after the original course. In this case, there would be *two* control groups:

1. the same unimmunized cohort, as before; and
2. a group of children previously vaccinated, whose parents decided not to give them a "booster" dose.

This study would also measure the incidence and morbidity of the acute disease when it *does* break out, rather than simply the circulating antibody titer, which is probably far less relevant.

My conjecture, based on the preliminary studies I cited in the text, is that both primary and booster vaccinations tend to give considerably less protection against the corresponding acute disease when it does break out than the simple drop in incidence, or the rise in antibody titer, would indicate.

Both of these studies could also be carried out in suitable animal populations, using vaccines developed against disease peculiar to each species, such as canine distemper, leptospiro and the like, inasmuch as what we are concerned with includes the effectiveness and mode of action of the vaccines in general.

A third possibility would be to investigate the relationship between circulating antibody and "immunity" in the above sense. This could be done by measuring antibody titer periodically in a large pooled sample, and then retrospectively comparing baseline titers in an immunized group that subsequently developed the disease with another immunized group that was exposed to the disease but did not develop it. Both could then be compared with the corresponding nonimmunized groups, who would be expected to show no measurable titers at all prior to exposure.

2. *How Do the Vaccines Act?*

The problem with all of these studies is that they systematically ignore the crucial possibility that the vaccines may act immunosuppressively, and may therefore produce or at least promote a variety of obscure chronic diseases over long periods of time. This is why the "effectiveness" of the vaccines cannot really be studied in isolation without first understanding their mode of action in a more comprehensive fashion.

Indeed, the issue of effectiveness is actually misleading, insofar as it leads us to focus on the typical acute disease, rather than the broad spectrum of biological effects that can be associated with bacteria, viruses, and the vaccines derived from them, a spectrum that includes latent, subclinical, and chronic phenomena as well. We certainly know of situations in which *inability* to develop acute disease represents the exact opposite of good health, i.e., the consequences of chronic immune tolerance rather than true immunity.

At the crudest level, then, we need to study the effects of the vaccines, both acutely and long-term, on various clinical and laboratory parameters of health and disease. In the case of the pertussis vaccine, for example, we need good prospective studies on the incidence and severity of various hematological and CNS abnormalities over time, following the administration of the single vaccine at the usual time (and at routine intervals before and after). This could be done simply and inexpensively by performing CBCs, brief neurological exams, and behavioral assessments on the same self-selected groups of immunized and unimmunized children.

Another method would be to follow certain obvious *clinical* variables at the time of the normal well-child and other pediatric visits, such as the incidence and severity of acute and recurrent URI, tonsillitis, pharyngitis, otitis media, cervical adenopathy, and the like, in both immunized and unimmunized children over a period of years.

The same experimental format should also make it possible to sort out the various patterns of chronic morbidity following each individual vaccine. Again, the crucial importance of the unimmunized cohort becomes obvious. With regard to pertussis, for example, my clinical experience to date strongly suggests that the immunized group will have a significantly higher incidence and morbidity from chronic and recurrent infections, with higher rates of complications and disability, such as myringotomies, hearing loss, etc.

A long-term study could then follow these same children through older childhood and adolescence, to determine the incidence and morbidity of various chronic disease, such as eczema, asthma, rheumatoid arthritis, SLE, ulcerative colitis, multiple sclerosis, and other idiopathic degenerative, CNS, or connective-tissue diseases, as well as mental retardation, hyperactivity, school and behavior problems, convulsive disorders, leukemia, and other forms of cancer. Once again, my suspicion is that the immunized group would show a significantly higher increase in the incidence and morbidity in all these categories. I *hope* I'm wrong, but I don't think I am.

Another interesting and useful study would be to measure the effect of the common vaccines on the incidence and morbidity of other acute infections to which the individual was definitely or probably exposed (influenza, hepatitis, genital herpes, Colorado tick fever, etc.). The point here would be to see if the vaccination process has any effect on the capacity of the immune system to deal with acute infection generally, which seems quite probable.

In this case there would be two control groups:

1. one group of children not previously immunized (against measles, mumps, or whatever), who were subsequently exposed to influenza, hepatitis, or some other acute infection; and
2. a group of similar children who contracted and recovered from acute measles, mumps, or whatever, some time before their exposure to influenza, hepatitis, etc.

Again, my conjecture is that both groups, while perhaps no less likely

to *contract* the second disease, would show significantly less acute and chronic *morbidity* as a result of it.

Along these same lines, it would not be very difficult to design some good animal studies investigating the possibility of immunosuppression by the vaccines. This could be done by measuring leukocyte and macrophage activity both in vivo and in vitro, in response to various challenges, such as exposure to unrelated infections, allergens, and chemicals. Various liver function tests, as well as the ability of the spleen and bone marrow to respond to hemorrhage and blood transfusion could also be followed. Finally, the ability of both immunized and unimmunized animals to reject homografts could be measured quite easily.

Careful cytogenetic studies could also be made, to show the effects of vaccination on karyotype and chromosome morphology, beginning with typical "target" cells for which the vaccine in question has a known affinity (e.g., liver parenchymal cells in hepatitis, parotid acinar cells in mumps, cells of the nasal mucosa in measles). Careful virological studies of these same cells should also make it possible to recover or at least demonstrate the existence of episomes or viral nucleoprotein moieties within the DNA or RNA of the host, which would confirm the suspicion of latency and chronic infection, at least in the case of the live vaccine.

But, whichever studies are done, the point is that the technology to do them already exists; and the only thing that prevents them from being done is our own ideological resistance to the self-evident truth that vaccines are not simply "wonder drugs" that produce specific antibodies and nothing more, but complex, biologically active substances whose effects on the human organism urgently need to be investigated.

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QUESTION AND ANSWER PERIOD

Q: Why does the American Academy of Pediatrics draft a bill for compensation of vaccine-damaged children that we taxpayers will have to pay for? Why don't the pharmaceutical companies and the doctors and legislators pay for this damage?

Lori Andrews: Before you answer the questions, I'm going to make a suggestion, since I know that the subject of immunization evokes a lot

of interest. I wonder if we could get a number of questions and comments first and then you might answer them as a group, and then everybody can have their chance to talk.

Q: How many cases have you found that had cancer developed at the site of the injection? Can you elaborate on Senate Bill S.2117, as to why the taxpayer should not be used to compensate the vaccine-damaged children? In my opinion, epidemics are pharmaceutical clearance sales. Epidemics are seasonal events. All vaccines are iatrogenic. Today's immunized children are tomorrow's asthmatics, diabetics, and cancer victims.

Q: I'd like to make a comment: I recently met a man who had vaccinations 60 years ago. The left half of his body is completely raw and they determined it's all vaccination, just growing in his body. My question is: Since laws on immunizations are enforced more and more, it is our legislators that pass these laws after the lobbyists have talked them into passing the laws. Who are the people who pay the lobbyists to force the immunizations?

Q: Are you familiar at all with John Chris Hofman's work, University of Maryland? He has speculated that vaccine-induced immunity commits more of the body's immune system to that particular antigen, which means they are less available for nonspecific reactions. Have you in your research come across any support for that speculation, and what are your own feelings on that?

Q: I've read some of your other articles on immunizations, and I'd like to know exactly how, in your opinion, a homeopathically prepared remedy would work as opposed to immunization shots. What is the physiology of what actually takes place biologically?

Q: I'd like to know if you know of any cases where the breast on the opposite side of where the vaccination was to be removed? We know of a lot of them that were on the same side where the vaccine was, but haven't found anybody yet that really had it on the opposite side.

Q: Your talk has been very educational for me, and my question is: What if you refuse shots? I know last year Chicago had a big thing about if you didn't have shots you couldn't get back into the school, and I want to know what options you have if you definitely refuse to have your children vaccinated.

Q: Dr. Moskowitz, from the credits that we heard at the beginning of your speech, I take it that you're not a resident of Illinois, but live in Massachusetts. In response to the question that was just asked—what do parents do for enforced immunizations perpetrated by the school system

and the public health authority?—the answer is simple. You have to fight the bastards in court. That's it; it just has to be done that way. I apologize for being so rude, but that, in fact, is the case, because the laws are such that you just have no choice. That's why I think, Dr. Mendelsohn, that immunizations evoke such response from the public, because it is the area in which the freedom of choice of the people is really being taken away from them and they can do very little about it.

Dr. Moskowitz: Maybe I can address some of those questions now. First of all, the lady who asked about cancer at the injection site: No, I have never seen such a thing. It may be possible, but I personally have not seen it or heard of it. In fact, I'd be interested in knowing any documentation you might have of that.

As far as the bill compensating victims of vaccination, I'm opposed to that bill because I think that basically the bill is an attempt to maintain the system as we have it. The American Academy of Pediatrics was challenged by Congress to come up with some guidelines to compensate vaccine-injured people and basically what they came up with is that in order to prove that the victim was injured by the vaccine, they have to show first of all that the effect happened within 30 days of the administration of the vaccine and, secondly, that it has to be an effect that's already been studied or already been discovered. That eliminates immediately the whole concern of my paper, which is precisely those chronic things that happen later, that may be very insidious and very difficult to trace, and for which we as yet have no adequate experimental evidence. So, I think that's a very shortsighted bill and I think really the purpose of it is simply to continue compulsory immunization. I think the bill is paying off a few, a very, very few people, just the very tip of that iceberg there, and the rest of it is being left not only unpaid but uninvestigated as well. That's the whole point of what I'm trying to say, that we need new laws to make those vaccines voluntary. They are in some states; some states have changed the laws in this respect.

As far as the third question goes, I'm not familiar with Dr. Hotman's work, and I'd be very interested in it; but my feeling is that that's only a very small part of what happens because I think the nonspecific immunity is also very important and is probably the reason why measles evolved from a killer disease, which it was at one time. When it was introduced by Cortez into the Americas as the secret weapon of the conquistadores, it decimated whole populations of Mexican villages. It's been estimated to kill about 20 percent of the people infected with it

when it meets a population for the first time. The evolution of a disease like measles from a killer into a more or less common disease of childhood which is handled very effectively by the vast majority of people in a population requires generations and generations of what you might call nonspecific or herd immunity, such that when the disease actually strikes, the immune mechanism is already in place waiting for it. So, I think those nonspecific responses are very, very important for the development of what we call true immunity, lifelong immunity, such as you get from recovering from a natural disease.

As far as the homeopathic remedies are concerned, I honestly do not know how the homeopathic remedies work and cannot as yet give you a convincing explanation of how substances as dilute as that can work. We know that they work; we've had the *experience* that they work, and it's a very beautiful, elegant, and safe method. But it implies the existence of a science that in a sense has not been discovered yet, although we're working on it, and trying very hard to elaborate it. I certainly would not say that it's a panacea for every patient with vaccine-related illness, but it certainly can help in many cases.

Someone alluded to the possibility of using a homeopathic remedy in lieu of vaccine. There were homeopaths who advocated that, and indeed there are some people who still do. I myself do not do it because I think the immunization laws are concerned with *long-term* immunity. In order to do that with a homeopathic remedy you would have to give it many, many times, and that's a usage that I would not support. I don't think that long-term immunity is really possible, or even desirable, using artificial means.

As far as the vaccine on the same side as the breast cancer, there again, you've got me; I've never heard of that before. It's very interesting, and I'd like very much to see the information you've collected about it.

As far as the question about the school requirements, I would say that it varies quite a bit from state to state and even from school district to school district. For example, Indiana is one of the many states that, partly in response to public outcry, changed its law so that people may waive the requirement for their children to be immunized if they have a strong philosophical objection to it. They have to sign a waiver that the state gives them; but, even in a state like that, where the law is on the books, to get a school board to allow that may be very difficult. It may take a telephone call from a lawyer or something to let them know that you're really serious to honor the law that exists.

In many other states, in Maryland, for example, the law is quite rigid and without exception: There are no exceptions, except in some cases, if the doctor writes a letter of exemption for very strong medical reasons, such as for a child who has a high fever or convulsions at the time of the test. In that case everyone would agree that the immunization should not be given. If there was a strong history of neurological disease, they might also entertain such a letter; but this whole area that we were getting into here about the connection between vaccines and chronic disease would not be allowed at present in a state such as Maryland.

It is the intent of the Legislature that the Department of Health and Social Services shall report to the 16th Legislature no later than April 1, 1989 as to the federal regulations promulgated by both the Federal Drug Administration and Department of Health and Human Services regarding the use of vaccines and the resulting Alaska program; its requirements regarding specific information which must be provided to the guardians of minors to be vaccinated and the manner in which adverse reactions must be reported.

ALASKA STATE LEGISLATURE
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April 19, 1988

MEMORANDUM

TO: Representative Niilo Koponen

ATTN: Lisa McLaren

FROM: Patricia Brawley pb
Legislative Analyst

RE: Vaccination Information Requirements
Research Request 88.240

You wished to know 1) if any states require both public and private sector health care providers to inform vaccine recipients, their parents, or legal guardians about the vaccines and their potential adverse effects, and 2) if statutes of states which require dissemination of information include provisions for enforcement and penalties for noncompliance. As background for this question, I will discuss access to and control of vaccines, as well as current and future requirements for health care providers who administer them.

Vaccines--Access and Control

In the United States, vaccines are either publicly or privately purchased. Privately purchased vaccines can be bought directly from drug manufacturers. Adverse reactions resulting from privately purchased vaccines are reported to the Food and Drug Administration (FDA). According to Ken Allman, Public Health Advisor at the Centers for Disease Control (CDC) in Atlanta, vaccines are generally purchased by states through a contract with the federal government. State or local money is used, and vaccines are distributed throughout the public sector. One stipulation of this contract is that public health care providers who administer these vaccines also dispense an "important information statement" which provides background information on the disease and the antigen, risks and benefits of the vaccine, contraindication, signs and symptoms of possible adverse reactions, and what to do and who to call in case of adverse reactions. Another stipulation involves use of the Monitoring System for Adverse Events Following Immunization (MSAEFI) developed by the Centers for Disease Control.

The contract between the federal and state governments requires that public sector health care providers comply with these stipulations as a condition of receiving vaccines from the state agency which purchased them. According to Elfrida Nord, Chief of Nursing, Department of Health and Social Services (DHSS), Alaska was one of the last states to accept the federal vaccine program and its attendant regulations. Until January 1985, when the federal contract became more attractive due to state funding considerations, Alaska purchased vaccines directly from manufacturers.

In some states--such as Alaska--private sector providers may receive publicly purchased vaccines from the public sector agencies. In Alaska, vaccines are made available at no cost to public health care providers, and to private physicians who request them. Private sector health care providers have been encouraged to use the information statements and reporting forms, but because the public sector has no jurisdiction over the private sector, there has been no enforcement. Although not required to use the information statements, many physicians obtain vaccines directly from the manufacturers, preferring direct access to low cost.

State Legislation Requiring Information Prior to Vaccinations

Information and reporting requirements were incorporated into the federal contract largely as a result of lobbying efforts by Dissatisfied Parents Together (DPT), a group opposed to mandatory DPT vaccinations--specifically, to the pertussis (P) component of the vaccination. Because the federal regulations did not adequately extend to private sector providers, both Maryland and New Jersey addressed this problem (for pertussis vaccinations only) by requiring that all health care providers give written information to the parents or legal guardians of children prior to their children receiving immunizations for pertussis. Neither statute contains provisions for enforcement or penalties for noncompliance.

Recent Federal Regulations

As you may know, the National Childhood Vaccine Injury Act of 1986, which established the National Vaccine Injury Compensation Program, became effective on March 22, 1988. Intended to assure a safer childhood vaccination program in the U.S., this Act will improve the systems for reporting adverse reactions and standardize the use of important information statements prior to the administration of the vaccines. Under the new law, all health care providers will permanently record certain vital information, and will report any adverse reaction or event described in the Vaccine

Injury Tables which occurs within a specified time after the date of vaccination.[1] Information requirements are being developed and will include the following:

> . . . each health care provider who administers a vaccine set forth in the Vaccine Injury Table shall provide to the legal representatives of any child to whom such provider intends to administer such vaccine a copy of the information materials developed . . . or other written information which meets the requirements of this section. Such materials or other information shall be provided prior to the administration of such vaccine. . . . The information in such materials shall be presented in understandable terms and shall include--
>
> 1) the frequency, severity, and potential long-term effects of the disease to be prevented by the vaccine,
>
> 2) the symptoms or reactions to the vaccine which, if they occur, should be brought to the immediate attention of the health care provider,
>
> 3) precautionary measures legal representatives should take to reduce the risk of any major adverse reactions to the vaccine that may occur,
>
> 4) early warning signs or symptoms to which legal representatives should be alert as possible precursors to such major adverse reactions,
>
> 5) a description of the manner in which legal representatives should monitor such major adverse reactions, including a form on which reactions can be recorded to assist legal representatives in reporting information to appropriate authorities,

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[1]Memorandum from Alan R. Hinman, Director, Center for Prevention Services, CDC, to Immunization Project Directors, March 21, 1988, and CDC, "National Childhood Vaccine Injury Act: Requirements for Permanent Vaccination Records and for Reporting of Selected Events After Vaccination," Morbidity and Mortality Weekly Report, April 8, 1988, pp. 197 - 200, Attachment A.

6) a specification of when, how, and to whom legal representatives should report any major adverse reaction,

7) the contraindications to (and bases [sic] for delay of) the administration of the vaccine,

8) an identification of the groups, categories, or characteristics of potential recipients of the vaccine who may be at significantly higher risk of major adverse reaction to the vaccine than the general population,

9) a summary of relevant State and Federal laws concerning the vaccine, including information on--

   A) the number of vaccinations required for school attendance and the schedule recommended for such vaccinations, and

   B) the availability of the Program, and

10) such other relevant information as may be determined by the Secretary. [See Attachment B for full text.]

There are no provisions in the new federal law for enforcement or penalties for noncompliance, other than for manufacturers who intentionally misrepresent information. According to representatives of the CDC, however, the injury compensation program and growing public awareness of problems associated with vaccines make the use of both information statements and reporting systems more desirable for all health care providers.

I have requested that the CDC send copies of both current and future "important information statements" to your office. I hope this information is useful to you. If you need further information, please call.

Attachments

ATTACHMENT A

Memorandum from Alan R. Hinman, Director,
Center for Prevention Services, CDC, to Immunization
Project Directors, March 21, 1988, and CDC, "National Childhood Vaccine
Injury Act: Requirements for Permanent Vaccination Records
and for Reporting of Selected Events After Vaccination,"
Morbidity and Mortality Weekly Report, April 8, 1988

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
Atlanta GA 30333

March 21, 1988

TO : Immunization Project Directors

SUBJECT: National Vaccine Injury Compensation Program: Legal Requirements for Reporting of Events Following Vaccination Beginning March 22, 1988

As a result of the National Vaccine Injury Act of 1986, which established the National Vaccine Injury Compensation Program, and amendments enacted as of December 22, 1987, all providers of vaccinations will be required to report selected adverse events for selected vaccines to the Federal government. The requirement becomes effective March 22, 1988.

Attached to this memorandum is a draft of an article describing Program reporting requirements and the system(s) to use for reporting adverse events. This article will be published in the Morbidity and Mortality Weekly Report (MMWR) and most likely in the Food and Drug Administration (FDA) Bulletin. For public sector immunization programs nationwide, the most important point to be extracted from the article, is that, at least for the interim, adverse events following immunization with selected publicly-funded vaccines that require reporting under the Program are to be reported through the Monitoring System for Adverse Events Following Immunization (MSAEFI) using the current Adverse Event Following Immunization form (CDC form 71.19) available in each State. The current MSAEFI program encompasses the reporting requirements of the National Vaccine Injury Compensation Program. While no punitive measures for nonreporting are designated within the law, increased reporting of events (including those following publicly-funded vaccines) can be anticipated because of increased awareness of the law among providers of vaccine and among the public. How great this increase might be in the public sector is difficult to envision at this time, but the Division of Immunization will monitor this closely.

The attachment also outlines the system to be used by providers of privately purchased vaccines to report selected events following selected vaccines. Basically, such reports are to be made directly to the FDA on its Adverse Reaction Report (FDA form 1639). This form is currently in use for adverse event reporting after receipt of drugs and biologics such as vaccines. The FDA, like the Division of Immunization, will be quantitating the impact of the reporting requirement on its workload.

Some confusion will arise among some vaccine providers concerning the systems for reporting both publicly and privately purchased vaccines. Local, county, and State immunization and other public health personnel are likely to be contacted by vaccine providers to clarify the what, the how, and the where of reporting. The content and tables of the attachment can be used for this purpose.

Active consideration is being given to developing a single reporting system to accommodate reports of events after both publicly and privately purchased vaccines. Several options have been outlined, and the costs and logistics of each are being developed and discussed. It will be some time before a decision is made and such a system made available to replace the systems outlined in this memorandum and this attachment.

Finally, we want to emphasize that the Adverse Event Following Immunization form should continue to be completed and sent by States to CDC for any adverse event following receipt of any publicly purchased vaccine that had onset within 28 days of vaccination and for which the vaccine recipient was seen by a health care provider. We continue to be most appreciative of the ongoing support given to MSAEFI by public health personnel at all levels.

Your help in distributing the content of this memorandum to pertinent immunization personnel who may be responsible for the current public sector adverse event reporting system, and to other health department personnel who may be in a position to answer health care provider and public inquiries would be most appreciated. Any questions concerning reporting from program personnel should be addressed to Edward W. Brink, M.D., (404) 639-1867.

Alan Hinman

Alan R. Hinman, M.D.
Director
Center for Prevention Services

Attachment (Draft of MMWR. April 8, 1988, pp. 197-200.)

cc:
Regional Offices
Immunization Program Managers
MSAEFI Coordinators
Association of State and Territorial
Health Officers
Conference of State and Territorial Epidemiologists

CENTERS FOR DISEASE CONTROL

April 8, 1988 / Vol. 37 / No. 13

MMWR

MORBIDITY AND MORTALITY WEEKLY REPORT

Current Trends

National Childhood Vaccine Injury Act: Requirements for Permanent Vaccination Records and for Reporting of Selected Events After Vaccination

Since March 21, 1988, health-care providers who administer certain vaccines and toxoids are required by law to record permanently certain information and to report certain events.* The vaccines and toxoids to which these requirements apply follow: diphtheria and tetanus toxoids and pertussis vaccine (DTP); pertussis vaccine (P); measles, mumps, and rubella single-antigen vaccines and combination vaccines (MMR, MR); diphtheria and tetanus toxoids (DT); tetanus and diphtheria toxoids (Td); tetanus toxoid (T); poliovirus vaccine live, oral (OPV); and poliovirus vaccine inactivated (IPV) (Table 1). The requirements also will apply to DTP combined with inactivated poliovirus vaccine (DTP/Polio combined) if it becomes available.

Requirements for Recording

Specifically, all health-care providers who administer one or more of these vaccines or toxoids are required to ensure that there is recorded in the vaccine recipient's permanent medical record (or in a permanent office log or file) the date the vaccine was administered, the manufacturer and lot number of the vaccine, and the name, address, and title of the person administering the vaccine. The term health-care provider is defined as any licensed health-care professional, organization, or institution, whether private or public (including federal, state, and local departments and agencies), under whose authority a specified vaccine is administered.

Requirements for Reporting

Health-care providers are required to report to the U.S. Department of Health and Human Services (DHHS) selected events occurring after vaccination. Reportable events applicable to the previously mentioned vaccines and toxoids are shown in Table 1 and include events described in the vaccine manufacturer's package insert as contraindications to receiving additional doses of the vaccine.

*The National Childhood Vaccine Injury Act of 1986, at Section 2125 of the Public Health Service Act as codified at 42 U.S.C. § 300aa-25 (Supp. 1987).

Vaccine – Continued

TABLE 1. Reportable events following vaccination

Vaccine/Toxoid	Event	Interval from Vaccination
DTP, P, DTP/Polio Combined	A. Anaphylaxis or anaphylactic shock	24 hours
	B. Encephalopathy (or encephalitis)*	7 days
	C. Shock-collapse or hypotonic-hyporesponsive collapse*	7 days
	D. Residual seizure disorder*	(See Aids to Interpretation*)
	E. Any acute complication or sequela (including death) of above events	No limit
	F. Events in vaccinees described in manufacturer's package insert as contraindications to additional doses of vaccine† (such as convulsions)	(See package insert)
Measles, Mumps, and Rubella; DT, Td, Tetanus Toxoid	A. Anaphylaxis or anaphylactic shock	24 hours
	B. Encephalopathy (or encephalitis)*	15 days for measles, mumps, and rubella vaccines; 7 days for DT, Td, and T toxoids
	C. Residual seizure disorder*	(See Aids to Interpretation*)
	D. Any acute complication or sequela (including death) of above events	No limit
	E. Events in vaccinees described in manufacturer's package insert as contraindications to additional doses of vaccine†	(See package insert)
Oral Polio Vaccine	A. Paralytic poliomyelitis	
	—in a non-immunodeficient recipient	30 days
	—in an immunodeficient recipient	6 months
	—in a vaccine-associated community case	No limit
	B. Any acute complication or sequela (including death) of above events	No limit
	C. Events in vaccinees described in manufacturer's package insert as contraindications to additional doses of vaccine†	(See package insert)
Inactivated Polio Vaccine	A. Anaphylaxis or anaphylactic shock	24 hours
	B. Any acute complication or sequela (including death) of above event	No limit
	C. Events in vaccinees described in manufacturer's package insert as contraindications to additional doses of vaccine†	(See package insert)

*Aids to Interpretation:

Shock-collapse or hypotonic-hyporesponsive collapse may be evidenced by signs or symptoms such as decrease in or loss of muscle tone, paralysis (partial or complete), hemiplegia, hemiparesis, loss of color or turning pale white or blue, unresponsiveness to environmental stimuli, depression of or loss of consciousness, prolonged sleeping with difficulty arousing, or cardiovascular or respiratory arrest.

Residual seizure disorder may be considered to have occurred if no other seizure or convulsion unaccompanied by fever or accompanied by a fever of less than 102° F occurred before the first seizure or convulsion after the administration of the vaccine involved.

AND, if in the case of measles-, mumps-, or rubella-containing vaccines, the first seizure or convulsion occurred within 15 days after vaccination OR in the case of any other vaccine, the first seizure or convulsion occurred within 3 days after vaccination,

AND, if two or more seizures or convulsions unaccompanied by fever or accompanied by a fever of less than 102° F occurred within 1 year after vaccination.

The terms seizure and convulsion include grand mal, petit mal, absence, myoclonic, tonic clonic, and focal motor seizures and signs. Encephalopathy means any significant acquired abnormality of, injury to, or impairment of function of the brain. Among the frequent manifestations of encephalopathy are focal and diffuse neurologic signs, increased intracranial pressure, or changes lasting at least 6 hours in level of consciousness, with or without convulsions. The neurologic signs and symptoms of encephalopathy may be temporary with complete recovery, or they may result in various degrees of permanent impairment. Signs and symptoms such as high-pitched and unusual screaming, persistent unconsolable crying, and bulging fontanel are compatible with an encephalopathy, but in and of themselves are not conclusive evidence of encephalopathy. Encephalopathy usually can be documented by slow wave activity on an electroencephalogram.

†The health-care provider must refer to the CONTRAINDICATION section of the manufacturer's package insert for each vaccine.

Vaccine – Continued

Methods for Reporting

In the United States, vaccines are either publicly or privately purchased. Publicly purchased vaccines are bought with federal, state, and/or local government funds. At present, the method and route for reporting adverse events depend on whether the vaccine administered is publicly or privately purchased. Events occurring after receipt of publicly purchased vaccines are reported through local, county, and/or state health departments to the Centers for Disease Control (CDC) on its Report of Adverse Events Following Immunization (CDC form 71.19). Events occurring after receipt of a privately purchased vaccine usually are reported directly to the Food and Drug Administration (FDA) on its Adverse Reaction Report (FDA form 1639) by the health-care provider or the manufacturer.

For the time being, these two systems for reporting adverse events are to be used to implement the requirement of Title XXI of the Public Health Service Act for reporting adverse events to DHHS (Table 2).

Reportable events occurring after receipt of a publicly purchased vaccine shall be reported to local, county, and/or state health departments through channels currently in place at those institutions. The Report of Adverse Events Following Immunization, available at each state health department, shall be completed and sent by the state health department to CDC.

TABLE 2. Reporting of events occurring after vaccination

	Vaccine Purchased with Public Money	Vaccine Purchased with Private Money
Who Reports:	Health-care provider who administered the vaccine	Health-care provider who administered the vaccine
What Products To Report:	DTP, P, Measles, Mumps, Rubella, DT, Td, T, OPV, IPV, and DTP/Polio Combined	DTP, P, Measles, Mumps, Rubella, DT, Td, T, OPV, IPV, and DTP/Polio Combined
What Reactions To Report:	Events listed in Table 1 including contraindicating reactions specified in manufacturers' package inserts	Events listed in Table 1 including contraindicating reactions specified in manufacturers' package inserts
How To Report:	Initial report taken by local, county, or state health department. State health department completes CDC form 71.19	Health-care provider completes Adverse Reaction Report-FDA form 1639 (include interval from vaccination, manufacturer, and lot number on form)
Where To Report:	State health department sends CDC form 71.19 to MSAEFI/IM (E05) Centers for Disease Control Atlanta, GA 30333	Completed FDA form 1639 is sent to Food and Drug Administration (HFN-730) Rockville, MD 20857
Where To Obtain Forms:	State health departments	FDA and publications such as *FDA Drug Bu...*

ATTACHMENT B

The National Childhood Vaccine Injury Act of 1986

Legislative History. For legislative history and purpose of Pub.L. 98–512, see 1984 U.S.Code Cong. and Adm.News, p. 4095.

Library References
United States ⇐82.
C.J.S. United States § 122.

§ 300z–10. Restrictions

Library References
United States ⇐82.
C.J.S. United States § 122.

SUBCHAPTER XIX—VACCINES

PART 1—NATIONAL VACCINE PROGRAM

§ 300aa–1. Establishment

The Secretary shall establish in the Department of Health and Human Services a National Vaccine Program to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines. The Program shall be administered by a Director selected by the Secretary.

(July 1, 1944, c. 373, Title XXI, § 2101, as added Nov. 14, 1986, Pub.L. 99–660, Title III, § 311(a), 100 Stat. 3756.)

Effective Date. Section 323 of Pub.L. 99–660 provided that:

"(a) **General rule.**—Part 1 of title XXI of the Public Health Service Act [part 1 of this subchapter] shall take effect on the date of the enactment of this Act [Nov. 14, 1986] and Subtitle 2 of such title [part 2 of this subchapter] and this title [see Short Title note under section 201 of this title] shall take effect on the effective date of a tax enacted after the date of the enactment of this Act to provide funds for compensation paid under such subtitle 2.

"(b) **Insufficiency of funds.**—If at any time there are insufficient funds to pay all of the claims payable under subtitle 2 of title XXI of the Public Health Service Act [part 2 of this subchapter] for 180 days, such subtitle shall cease to be in effect until sufficient funds to pay all of the claims under such subtitle become available."

Study of Relationship between Vaccines Containing Pertussis and Certain Illnesses. Section 312 of Pub.L. 99–660 provided that:

"(a) **Review of pertussis vaccines and related illnesses and conditions.**—Not later than 3 years after the effective date of this title [see section 323 of Pub.L. 99–660 set out as a note under this section], the Secretary of Health and Human Services shall complete a review of all relevant medical and scientific information (including information obtained from the studies required under subsection (e)) on the nature, circumstances, and extent of the relationship, if any, between vaccines containing pertussis (including whole cell, extracts, and specific antigens) and the following illnesses and conditions:

"(1) Hemolytic anemia.

"(2) Hypoarrhythmia.

"(3) Infantile spasms.

"(4) Reye's syndrome.

"(5) Peripheral mononeuropathy.

"(7) Aseptic meningitis.

"(8) Juvenile diabetes.

"(9) Autism.

"(10) Learning disabilities.

"(11) Hyperactivity.

"(12) Such other illnesses and conditions as the Secretary may choose to review or as the Advisory Commission on Childhood Vaccines established under section 2119 of the Public Health Service Act [section 300aa–19 of this title] recommends for inclusion in such review.

"The review under this subsection shall include notice and opportunity for a public hearing, consideration of written information submitted by the public, and consultation with such Advisory Commission.

"(b) **Findings with respect to pertussis.**—Not later than 3 years after the effective date of this title, the Secretary shall make, and publish in the Federal Register, the following specific findings:

"(1) Whether each of the illnesses or conditions set forth in subsection (a) can reasonably be determined in some circumstances to be caused or significantly aggravated, by pertussis-containing vaccines.

"(2) For each illness or condition for which a finding of causation or aggravation related to vaccines containing pertussis is made under paragraph (1), the circumstances under which such causation or aggravation can reasonably be determined to occur.

"(3) For each illness or condition for which a finding of causation or aggravation related to vaccines containing pertussis is made under paragraph (1), and for each illness or condition set forth in the Vaccine Injury Table under section 2114 of the Public Health Service Act [section 300aa–14 of this title] the time periods within which the first symptom or manifestation of onset or aggravation of each such illness [illegible] determined to

"(c) **Revision of table with respect to pertussis vaccines.**—At the same time the Secretary publishes in the Federal Register findings under subsection (b), the Secretary shall propose regulations to amend the Vaccine Injury Table under section 2114 of the Public Health Service Act [section 300aa–14 of this title] as a result of such findings. Not later than 42 months after the effective date of this title, the Secretary shall promulgate such proposed regulations with such modifications as may be necessary after opportunity for public hearing.

"(d) **Review of MMR vaccines and related illnesses and conditions.**—Not later than 3 years after the effective date of this title, the Secretary of Health and Human Services shall complete a review similar to the review conducted under subsection (a) with respect to the potential relationship between vaccines containing rubella (including MMR) and radiculoneuritis. The review under this subsection shall include notice and opportunity for a public hearing, consultation with the Advisory Commission on Childhood Vaccines and consideration of written information submitted by the public. Not later than 3 years after the effective date of this title, the Secretary shall make and publish in the Federal Register findings similar to those required by subsection (b) and shall, if appropriate, propose similar regulations (and thereafter promulgate such regulations) to those required by subsection (c), with respect to compensation under the National Vaccine Injury Compensation Program established under section 2110 of the Public Health Service Act [section 300aa–10 of this title] for radiculoneuritis caused, contributed to, or significantly aggravated by vaccines containing rubella.

"(e) **Pertussis and MMR studies.**—

"(1) In order to assist the Secretary in making the findings required under subsections (b) and (d), the Secretary shall, in accordance with subparagraph (B), arrange for the conduct of studies of—

"(A) the relationship between vaccines containing pertussis (including whole cell, extracts, and specific antigens) and the illnesses or conditions set forth in paragraphs (1) through (11) of subsection (a),

"(B) the relationship between vaccines containing pertussis and any other illnesses and conditions, as selected by the Secretary or the Advisory Commission on Childhood Vaccines established under section 2119 of the Public Health Service Act [section 300aa–19 of this title], and

"(C) the relationship between vaccines containing rubella (including MMR) and radiculoneuritis.

"(2)(A) The Secretary shall request the Institute of Medicine of the National Academy of Sciences to conduct the studies required by paragraph (1) under an arrangement by which the actual expenses incurred by such Academy in conducting such study will be paid by the Secretary.

"(B) If the Institute of Medicine is unwilling to conduct such study under such an arrangement, the Secretary shall enter into a similar arrangement with other appropriate nonprofit private groups or associations under which such groups or associations will conduct such study and prepare and submit the reports thereon as

"(C) The Institute of Medicine or other group or association conducting the studies required by paragraph (1) shall conduct such studies in consultation with the Advisory Commission on Childhood Vaccines established under section 2119 of the Public Health Service Act [section 300aa–19 of this title].

"(3) Reports on the results of the studies required by paragraph (1) shall be completed and submitted to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the State and to the Secretary not later than 32 months after the effective date of this title. Upon submission to the Secretary, the reports shall be made available to the public.

"(4) There are authorized to be appropriated such sums as are necessary for the purpose of making payments for the conduct of the studies required under this subsection.

"(f) **Definitions.**—For purposes of this section:

"(1) The term 'medical and scientific information' includes epidemiologic, clinical, biostatistical, pathological, toxicologic, and other laboratory data and case study information, observations, studies, and reports in peer-reviewed literature or official Government publications, as well as relevant unpublished information, data, studies, and observations.

"(2) The term 'MMR' means a vaccine containing material intended to prevent or confer immunity against measles, mumps, and rubella disease."

Study of Other Vaccine Risks. Section 313 of Pub.L. 99–660 provided that:

"(a) **Study.**—

"(1) Not later than 3 years after the effective date of this title [see section 323 of Pub.L. 99–660, set out as a note under this section] the Secretary shall, after consultation with the Advisory Commission on Childhood Vaccines established under section 2119 of the Public Health Service Act [section 300aa–19 of this title]—

"(A) arrange for a broad study of the risks (other than the risks considered under section 102) to children associated with each vaccine set forth in the Vaccine Injury Table under section 2114 of such Act [section 300aa–14 of this title] and

"(B) establish guidelines, after notice and opportunity for public hearing and consideration of all relevant medical and scientific information, respecting the administration of such vaccines which shall include—

"(i) the circumstances under which any such vaccine should not be administered,

"(ii) the circumstances under which administration of any such vaccine should be delayed beyond its usual time of administration, and

"(iii) the groups, categories, or characteristics of potential recipients of such vaccine who may be at significantly higher risk of major adverse reactions to such vaccine than the general population of potential recipients.

"(2)(A) The Secretary shall request the Institute of Medicine of the National Academy of

graph (1) under an arrangement by which the actual expenses incurred by such Academy in conducting such study will be paid by the Secretary.

"(B) If the Institute of Medicine is unwilling to conduct such study under such an arrangement, the Secretary shall enter into a similar arrangement with other appropriate nonprofit private groups or associations under which such groups or associations will conduct such study.

"(C) The Institute of Medicine or other group or association conducting the study required by paragraph (1) shall conduct such studies in consultation with the Advisory Commission on Childhood Vaccines established under section 2119 of the Public Health Service Act [section 300aa–19 of this title].

"(b) **Revision of guidelines.**—The Secretary shall periodically, but at least every 3 years after establishing guidelines under subsection (a), review and revise such guidelines after notice and opportunity for public hearing and consideration of all relevant medical and scientific information, unless the Secretary finds that on the basis of all relevant information no revision of such guidelines is warranted and publishes such finding in the Federal Register.

"(c) **Factors affecting guidelines.**—Guidelines under subsection (a) shall take into account—

"(1) the risk to potential recipients of the vaccines with respect to which the guidelines are established,

"(2) the medical and other characteristics of such potential recipients, and

"(3) the risks to the public of not having such vaccines administered.

"(d) **Dissemination.**—The Secretary shall widely disseminate the guidelines established under subsection (a) to—

"(1) physicians and other health care providers,

"(2) professional health associations,

"(3) State and local governments and agencies, and

"(4) other relevant entities."

Review of Warnings, Use Instructions and Precautionary Information Issued by Vaccine Manufacturers. Section 314 of Pub.L. 99-660 provided that: "Not later than 1 year after the effective date of this title [see section 323 of Pub.L. 99-660, set out as a note under this section] and after consultation with the Advisory Commission on Childhood Vaccines established under section 2119 of the Public Health Service Act [section 300aa-19 of this title] and with other appropriate entities, the Secretary of Health and Human Services shall review the warnings, use instructions, and precautionary information presently issued by manufacturers of vaccines set forth in the Vaccine Injury Table set out in section 2114 of the Public Health Service Act [section 300aa-14 of this title] and shall by rule determine whether such warnings, instructions, and information adequately warn health care providers of the nature and extent of dangers posed by such vaccines. If the Secretary determines that any such warning, instruction, or information is inadequate for such purpose in any respect, the Secretary shall at the same time require the manufacturers to revise and reissue such warning, instruction, or information as expeditiously as practical, but not later than 18 months after the effective date of this title."

Waiver of Paperwork Reduction. Section 321 of Pub.L. 99-660 provided that: "Chapter 35 of title 44, United States Code [44 U.S.C.A. § 3501 et seq.] shall not apply to information required for purposes of carrying out this title [Title III of Pub.L. 99-660, see Short Title of 1986 Amendment note set out under section 201 of this title] and implementing the amendments made by this title."

Nonseverability. Section 322 of Pub.L. 99-660 provided that: "If any provision of this title [Title III of Pub.L. 99-660, see Short Title of 1986 Amendment note set out under section 201 of this title] or the application of any provision of this title to any person or circumstance is held invalid by reason of a violation of the Constitution, the entire title shall be considered invalid."

Legislative History. For legislative history and purpose of Pub.L. 99-660, see 1986 U.S.Code Cong. and Adm.News, p. 6287.

§ 300aa–2. Program responsibilities

(a) The Director of the Program shall have the following responsibilities:

(1) Vaccine research

The Director of the Program shall, through the plan issued under section 300aa–3 of this title, coordinate and provide direction for research carried out in or through the National Institutes of Health, the Centers for Disease Control, the Office of Biologics Research and Review of the Food and Drug Administration, the Department of Defense, and the Agency for International Development on means to induce human immunity against naturally occurring infectious diseases and to prevent adverse reactions to vaccines.

(2) Vaccine development

The Director of the Program shall, through the plan issued under section 300aa–3 of this title, coordinate and provide direction for activities carried out in or through the National Institutes of Health, the Office of Biologics Research and Review of the Food and Drug Administration, the Department of Defense, and the Agency for International Development to develop the techniques needed to produce safe and effective vaccines.

(3) Safety and efficacy testing of vaccines

The Director of the Program shall, through the plan issued under section

300aa–3 of this title, coordinate and provide direction for testing of vaccines carried out in or through the National Institutes of Health, the Centers for Disease Control, the Office of Biologics Research and Review of the Food and Drug Administration, the Department of Defense, and the Agency for International Development.

(4) Licensing of vaccine manufacturers and vaccines

The Director of the Program shall, through the plan issued under section 300aa–3 of this title, coordinate and provide direction for the allocation of resources in the implementation of the licensing program under section 263a of this title.

(5) Production and procurement of vaccines

The Director of the Program shall, through the plan issued under section 300aa–3 of this title, ensure that the governmental and non-governmental production and procurement of safe and effective vaccines by the Public Health Service, the Department of Defense, and the Agency for International Development meet the needs of the United States population and fulfill commitments of the United States to prevent human infectious diseases in other countries.

(6) Distribution and use of vaccines

The Director of the Program shall, through the plan issued under section 300aa–3 of this title, coordinate and provide direction to the Centers for Disease Control and assistance to States, localities, and health practitioners in the distribution and use of vaccines, including efforts to encourage public acceptance of immunizations and to make health practitioners and the public aware of potential adverse reactions and contraindications to vaccines.

(7) Evaluating the need for and the effectiveness and adverse effects of vaccines and immunization activities

The Director of the Program shall, through the plan issued under section 300aa–3 of this title, coordinate and provide direction to the National Institutes of Health, the Centers for Disease Control, the Office of Biologics Research and Review of the Food and Drug Administration, the National Center for Health Statistics, the National Center for Health Services Research and Health Care Technology Assessment, and the Health Care Financing Administration in monitoring the need for and the effectiveness and adverse effects of vaccines and immunization activities.

(8) Coordinating governmental and non-governmental activities

The Director of the Program shall, through the plan issued under section 300aa–3 of this title, provide for the exchange of information between Federal agencies involved in the implementation of the Program and non-governmental entities engaged in the development and production of vaccines and in vaccine research and encourage the investment of non-governmental resources complementary to the governmental activities under the Program.

(9) Funding of federal agencies

The Director of the Program shall make available to Federal agencies involved in the implementation of the plan issued under section 300aa–3 of this title funds appropriated under section 300aa–6 of this title to supplement the funds otherwise available to such agencies for activities under the plan.

(b) In carrying out subsection (a) of this section and in preparing the plan under section 300aa–3 of this title, the Director shall consult with all Federal agencies involved in research on and development, testing, licensing, production, procurement, distribution, and use of vaccines.

(July 1, 1944, c. 373, Title XXI, § 2102, as added Nov. 14, 1986, Pub.L. 99–660, Title III, § 311(a), 100 Stat. 3756.)

Legislative History. For legislative history and purpose of Pub.L. 99–660, see 1986 U.S.Code Cong. and Adm.News, p. 6287.

§ 300aa–3. Plan

The Director of the Program shall prepare and issue a plan for the implementation of the responsibilities of the Director under section 300aa–2 of this title. The plan shall establish priorities in research and the development, testing, licensing, production, procurement, distribution, and effective use of vaccines, describe an optimal use

of resources to carry out such priorities, and describe how each of the various departments and agencies will carry out their vaccine functions in consultation and coordination with the Program and in conformity with such priorities. The first plan under this section shall be prepared not later than January 1, 1987, and shall be revised not later than January 1 of each succeeding year.

(July 1, 1944, c. 373, Title XXI, § 2103, as added Nov. 14, 1986, Pub.L. 99–660, Title III, § 311(a), 100 Stat. 3757.)

Legislative History. For legislative history and purpose of Pub.L. 99–660, see 1986 U.S.Code Cong. and Adm.News, p. 6287.

§ 300aa–4. Report

The Director shall report to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate not later than January 1, 1988, and annually thereafter on the implementation of the Program and the plan prepared under section 300aa–3 of this title.

(July 1, 1944, c. 373, Title XXI, § 2104, as added Nov. 14, 1986, Pub.L. 99–660, Title III, § 311(a), 100 Stat. 3757.)

Study of Impact on Supply of Vaccines. Section 316 of Pub.L. 99–660 provided that: "On June 30, 1987, and on June 30 of each second year thereafter, the Secretary of Health and Human Services shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate—

"(1) an assessment of the impact of the amendments made by this title on the supply of vaccines listed in the Vaccine Injury Table under section 2114 of the Public Health Service Act [42 U.S.C.A. § 300aa–14], and

"(2) an assessment of the ability of the administrators of vaccines (including public clinics and private administrators) to provide such vaccines to children."

Legislative History. For legislative history and purpose of Pub.L. 99–660, see 1986 U.S.Code Cong. and Adm.News, p. 6287.

§ 300aa–5. National Vaccine Advisory Committee

(a) There is established the National Vaccine Advisory Committee. The members of the Committee shall be appointed by the Director of the Program, in consultation with the National Academy of Sciences, from among individuals who are engaged in vaccine research or the manufacture of vaccines or who are physicians, members of parent organizations concerned with immunizations, or representatives of State or local health agencies or public health organizations.

(b) The Committee shall—

(1) study and recommend ways to encourage the availability of an adequate supply of safe and effective vaccination products in the States,

(2) recommend research priorities and other measures the Director of the Program should take to enhance the safety and efficacy of vaccines,

(3) advise the Director of the Program in the implementation of sections 300aa–2, 300aa–3, and 300aa–4 of this title, and

(4) identify annually for the Director of the Program the most important areas of government and non-government cooperation that should be considered in implementing sections 300aa–2, 300aa–3, and 300aa–4 of this title.

(July 1, 1944, c. 373, Title XXI, § 2105, as added Nov. 14, 1986, Pub.L. 99–660, Title III, § 311(a), 100 Stat. 3758.)

Legislative History. For legislative history and purpose of Pub.L. 99–660, see 1986 U.S.Code Cong. and Adm.News, p. 6287.

§ 300aa–6. Authorization of appropriations

(a) To carry out this part other than section 300aa–2(9) of this title there are authorized to be appropriated $2,000,000 for fiscal year 1987, $2,500,000 for fiscal year 1988, $3,000,000 for fiscal year 1989, $3,500,000 for fiscal year 1990, $4,000,000 for fiscal year 1991.

(b) To carry out section 300aa–2(9) of this title there are authorized to be

$25,000,000 for fiscal year 1989, $27,500,000 for fiscal year 1990, $30,000,000 for fiscal year 1991.

(July 1, 1944, c. 373, Title XXI, § 2106, as added Nov. 14, 1986, Pub.L. 99–660, Title III, § 311(a), 100 Stat. 3758.)

Legislative History. For legislative history and purpose of Pub.L. 99–660, see 1986 U.S.Code Cong. and Adm.News, p. 6287.

PART 2—NATIONAL VACCINE INJURY COMPENSATION PROGRAM

Subpart A—Program Requirements

§ 300aa–10. Establishment of program

(a) Program established

There is established the National Vaccine Injury Compensation Program to be administered by the Secretary under which compensation may be paid for a vaccine-related injury or death.

(b) Attorney's obligation

It shall be the ethical obligation of any attorney who is consulted by an individual with respect to a vaccine-related injury or death to advise such individual that compensation may be available under the program for such injury or death.

(July 1, 1944, c. 373, Title XXI, § 2110, as added Nov. 14, 1986, Pub.L. 99–660, Title III, § 311(a), 100 Stat. 3758.)

Legislative History. For legislative history and purpose of Pub.L. 99–660, see 1986 U.S.Code Cong. and Adm. News, p. 6287.

§ 300aa–11. Petitions for compensation

(a) General rule

(1) A proceeding for compensation under the Program for a vaccine-related injury or death shall be initiated by service upon the Secretary and the filing of a petition with the United States district court for the district in which the petitioner resides or in which the injury or death occurred.

(2)(A) No person may bring a civil action for damages in an amount greater than $1,000 or in an unspecified amount against a vaccine manufacturer in a State or Federal court for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after the effective date of this part, and no such court may award damages in an amount greater than $1,000 in a civil action for damages for such a vaccine-related injury or death, unless—

(i) a petition has been filed, in accordance with section 300aa–16 of this title, under subsection (b) of this section for compensation under the Program for such injury or death,

(ii) a district court of the United States has issued a judgment under section 300aa–12 of this title on such petition, and

(iii) such person elects under section 300aa–21(a) of this title to file such an action.

(B) If a civil action which is barred under subparagraph (A) is filed in a State or Federal court, the court shall dismiss the action. If a petition is filed under this section with respect to the injury or death for which such civil action was brought, the date such dismissed action was filed shall, for purposes of the limitations of actions prescribed by section 300aa–16 of this title, be considered the date the petition was filed if the petition was filed within one year of the date of the dismissal of the civil action.

(3) No vaccine manufacturer may be made a party to a civil action (other than a civil action which may be brought under paragraph (2)) for damages for a vaccine-related injury or death associated with the administration of a vaccine after the effective date of this subtitle.

(4) If in a civil action brought against a vaccine manufacturer before the effective date of this part damages were denied for a vaccine-related injury or death or if such civil action was dismissed with prejudice, the person who brought such action may file a petition under subsection (b) of this section for such injury or death.

(5)(A) A plaintiff who on the effective date of this subtitle has pending a civil action for damages for a vaccine-related injury or death may, at any time within 2 years after the effective date of this part or before judgment, whichever occurs first, elect to withdraw such action without prejudice and file a petition under subsection (b) of this section for such injury or death.

(B) If a plaintiff who on the effective date of this part had pending a civil action for damages for a vaccine-related injury or death does not withdraw the action under subparagraph (A), such person may not file a petition under subsection (b) of this section for such injury or death.

(6) If a person brings a civil action after the effective date of this part for damages for a vaccine-related injury or death associated with the administration of a vaccine before the effective date of this part, such person may not file a petition under subsection (b) of this section for such injury or death.

(7) If in a civil action brought against a vaccine manufacturer for a vaccine-related injury or death damages are awarded under a judgment of a court or a settlement of such action, the person who brought such action may not file a petition under subsection (b) of this section for such injury or death.

(b) Petitioners

(1)(A) Except as provided in subparagraph (B), any person who has sustained a vaccine-related injury, the legal representative of such person if such person is a minor or is disabled, or the legal representative of any person who died as the result of the administration of a vaccine set forth in the Vaccine Injury Table may file a petition for compensation under the Program.

(B) No person may file a petition for a vaccine-related injury or death associated with a vaccine administered before the effective date of this part if compensation has been paid under this part for 3500 petitions for such injuries or deaths.

(2) Only one petition may be filed with respect to each administration of a vaccine.

(c) Petition content

A petition for compensation under the Program for a vaccine-related injury or death shall contain—

(1) an affidavit, and supporting documentation, demonstrating that the person who suffered such injury or who died—

(A) received a vaccine set forth in the Vaccine Injury Table or, if such person did not receive such a vaccine, contracted polio, directly or indirectly, from another person who received an oral polio vaccine,

(B)(i) if such person received a vaccine set forth in the Vaccine Injury Table—

(I) received the vaccine in the United States or in its trust territories,

(II) received the vaccine outside the United States or a trust territory and at the time of the vaccination such person was a citizen of the United States serving abroad as a member of the Armed Forces or otherwise as an employee of the United States or a dependent of such a citizen, or

(III) received the vaccine outside the United States or a trust territory and the vaccine was manufactured by a vaccine manufacturer located in the United States and such person returned to the United States not later than 6 months after the date of the vaccination,

(ii) if such person did not receive such a vaccine but contracted polio from another person who received an oral polio vaccine, was a citizen of the United States or a dependent of such a citizen,

(C)(i) sustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table in association with the vaccine referred to in subparagraph (A) or died from the administration of such vaccine, and the first symptom or manifestation of the onset or of the significant aggravation of any such illness, disability, injury, or condition or the death occurred within the time period after vaccine administration set forth in the Vaccine Injury Table, or

(ii)(I) sustained, or had significantly aggravated, any illness, disability, injury, or condition not set forth in the Vaccine Injury Table but which was caused by a vaccine referred to in subparagraph (A), or

(II) sustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table the first symptom or manifestation of the onset or significant aggravation of which did not occur within the time period set forth in the Table but which was caused by a vaccine referred to in subparagraph (A),

(D)(i) suffered the residual effects or complications of such illness, disability, injury, or condition for more than 1 year after the administration of the vaccine, (ii) incurred unreimbursable expenses due in whole or in part to such illness, disability, injury, or condition in an amount greater than $1,000, or (iii) died from the administration of the vaccine, and

(E) has not previously collected an award or settlement of a civil action for damages for such vaccine-related injury or death,

(2) all available relevant medical records (including autopsy reports, if any) relating to the person who suffered such injury or who died from the administration of the vaccine and an identification of any unavailable records known to the petitioner and the reasons for their unavailability, and

(3) appropriate assessments, evaluations, and prognoses and such other records and documents as are reasonably necessary for the determination of the amount of compensation to be paid to, or on behalf of, the person who suffered such injury or who died from the administration of the vaccine.

(July 1, 1944, c. 373, Title XXI, § 2111, as added Nov. 14, 1986, Pub.L. 99–660, Title III, § 311(a), 100 Stat. 3758.)

References in Text. The effective date of this part, referred to in subsec. (a)(2)(A), (3), (4), (5)(A), (B), (6), (b)(1)(B), is the effective date of part II of subchapter XIX of this chapter which shall take effect on the effective date of a tax enacted after Nov. 14, 1986 to provide funds for compensation paid under such part 2, see section 323 of Pub.L. 99–660, set out as an Effective Date note under section 300aa–1 of this title.

Legislative History. For legislative history and purpose of Pub.L. 99–660, see 1986 U.S.Code Cong. and Adm. News, p. 6287.

§ 300aa–12. Court jurisdiction

(a) General rule

The district courts of the United States shall have jurisdiction (1) over proceedings to determine if a petitioner under section 300aa–11 of this title is entitled to compensation under the Program and the amount of such compensation, and (2) to issue and enforce such orders as the courts deem necessary to assure the prompt payment of any compensation awarded.

(b) Parties

(1) The Secretary shall be named as the respondent in all proceedings brought by the filing of a petition under section 300aa–11(b) of this title. Except as provided in paragraph (2), no other person may intervene in any such proceeding.

(2) Within 30 days after the Secretary receives service of any petition filed under section 300aa–11 of this title the Secretary shall publish notice of such petition in the Federal Register. The special master designated with respect to such petition under subsection (c) of this section shall afford all interested persons an opportunity to submit relevant, written information—

(A) relating to the existence of the evidence described in section 300aa–13(a)(1)(B) of this title, or

(B) relating to any allegation in a petition with respect to the matters described in section 300aa–11(c)(1)(C)(ii) of this title.

(c) Special masters

(1) Following receipt of a petition under subsection (a) of this section, the district court of the United States in which the petition is filed shall designate a special master to carry out the functions authorized by paragraph (2).

(2) A special master shall serve as an adjunct to the court and may—

(A) require such evidence as may be appropriate for the preparation of proposed findings of fact and conclusions of law with respect to whether compensation is to be provided under the Program and the amount of any such compensation,

(B) require the submission of such information as may be reasonable and necessary to determine if the petitioner is entitled to compensation,

(C) require the testimony of any person and the production of any document as may be reasonable and necessary to determine if the petitioner is entitled to compensation,

(D) conduct such hearings as may be appropriate, and

(E) prepare and submit to the court proposed findings of fact and conclusions of law.

Information submitted to a special master in a proceeding on a petition may not be disclosed to a person who is not a party to the proceeding without the express, written consent of the person who submitted the information. There may be no discovery in a proceeding on a petition other than the discovery required under this paragraph.

(d) Action by the court

(1) Upon objection by the petitioner or respondent to the proposed findings of fact or conclusions of law prepared by the special master or upon the court's own motion, the court shall undertake a review of the record of the proceedings and may thereafter make a de novo determination of any matter and issue its judgment accordingly, including findings of fact and conclusions of law, or remand for further proceedings.

(2) If no objection is filed under paragraph (1) or if the court does not choose to review the proceeding, the court shall adopt the proposed findings of fact and conclusions of law of the special master as its own and render judgment thereon.

(3) The court shall render its judgment on any petition filed under the Program as expeditiously as practicable but not later than 365 days after the date on which the petition was filed.

(e) Administration of award

The Program shall administer the payments of such compensation. The Program shall audit the payments of compensation under a judgment. A petitioner awarded compensation shall notify the Program of any changes which significantly affect the compensation to be paid.

(f) Revision of award

(1) If the court issues a judgment awarding to a petitioner compensation described in section 300aa–15(a)(1)(A) of this title for unreimbursable expenses and the compensation is insufficient to meet such expenses, such petitioner may petition the court to (A) review such award, and (B) increase the award to make it sufficient to meet such expenses or amend the periodic payment schedule established under section 300aa–15 of this title, or both.

(2) If an audit conducted under subsection (e) of this section discloses the improper use of compensation awarded under a judgment or the termination of a need for an item of compensation, the Program shall petition the court which awarded the compensation to make an appropriate revision in the compensation.

(g) Appeals

The findings of fact and conclusions of law of a district court of the United States on a petition shall be final determinations of the matters involved, except that the Secretary or any petitioner aggrieved by the findings or conclusions of the court may obtain review of the judgment of the court in the United States court of appeals for the circuit in which the court is located upon petition filed with such court of appeals.

(July 1, 1944, c. 373, Title XXI, § 2112, as added Nov. 14, 1986, Pub.L. 99–660, Title III, § 311(a), 100 Stat. 3761.)

Legislative History. For legislative history and purpose of Pub.L. 99–660, see 1986 U.S.Code Cong. and Adm. News, p. 6287.

§ 300aa–13. Determination of eligibility and compensation

(a) General rule

(1) Compensation shall be awarded under the Program to a petitioner if the court finds on the record as a whole—

(A) that the petitioner has demonstrated by a preponderance of the evidence the matters required in the petition by section 300aa–11(c)(1) of this title, and

(B) that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition.

The court may not make such a finding based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion.

(2) For purposes of paragraph (1), the term "factors unrelated to the administration of the vaccine"—

(A) does not include any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness, or condition, and

(B) may, as documented by the petitioner's evidence or other material in the record, include infection, toxins, trauma (including birth trauma and related anoxia), or metabolic disturbances which have no known relation to the vaccine involved, but which in the particular case are shown to have been the agent or agents principally responsible for causing the petitioner's illness, disability, injury, condition, or death.

(b) Matters to be considered

(1) In determining whether to award compensation to a petitioner under the Program, the court shall consider, in addition to all other relevant medical and scientific evidence contained in the record—

(A) any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death, and

(B) the results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions.

Any such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the court. In evaluating the weight to be afforded to any such diagnosis, conclusion, judgment, test result, report, or summary, the court shall consider the entire record and the course of the injury, disability, illness, or condition until the date of the judgment of the court.

(2) The court may find the first symptom or manifestation of onset or significant aggravation of an injury, disability, illness, condition, or death described in a petition occurred within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period. Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset or significant aggravation of the injury, disability, illness, condition, or death described in the petition did in fact occur within the time period described in the Vaccine Injury Table.

(c) Record defined

For purposes of this section, the term "record" means the record established by a district court of the United States in a proceeding on a petition filed under section 300aa–11 of this title.

(July 1, 1944, c. 373, Title XXI, § 2113, as added Nov. 14, 1986, Pub.L. 99–660, Title III, § 311(a), 100 Stat. 3763.)

Legislative History. For legislative history and purpose of Pub.L. 99–660, see 1986 U.S. Code

§ 300aa–14. Vaccine injury table

(a) Initial table

The following is a table of vaccines, the injuries, disabilities, illnesses, conditions, and deaths resulting from the administration of such vaccines, and the time period in which the first symptom or manifestation of onset or of the significant aggravation of such injuries, disabilities, illnesses, conditions, and deaths is to occur after vaccine administration for purposes of receiving compensation under the Program:

VACCINE INJURY TABLE

	Illness, disability, injury, or condition covered:	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration:
I.	DTP; P; DTP/Polio Combination; or Any Other Vaccine Containing Whole Cell Pertussis Bacteria, Extracted or Partial Cell Bacteria, or Specific Pertussis Antigen(s).	
	A. Anaphylaxis or anaphylactic shock	24 hours
	B. Encephalopathy (or encephalitis)	3 days
	C. Shock-collapse or hypotonic-hyporesponsive collapse	3 days
	D. Residual seizure disorder in accordance with subsection (c)(2)	3 days
	E. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed	Not applicable
II.	Measles, mumps, rubella, or any vaccine containing any of the foregoing as a component; DT; Td; or Tetanus Toxoid.	
	A. Anaphylaxis or anaphylactic shock	24 hours
	B. Encephalopathy (or encephalitis)	15 days (for mumps, rubella, measles, or any vaccine containing any of the foregoing as a component). 3 days (for DT, Td, or tetanus toxoid).
	C. Residual seizure disorder in accordance with subsection (c)(2)	15 days (for mumps, rubella, measles, or any vaccine containing any of the foregoing as a component). 3 days (for DT, Td, or tetanus toxoid).
	D. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed	Not applicable
III.	Polio Vaccines (other than Inactivated Polio Vaccine).	
	A. Paralytic polio	
	—In a non-immunodeficient recipient	30 days
	—In an immunodeficient recipient	6 months
	—In a vaccine-associated community case	Not applicable
	B. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed	Not applicable
IV.	Inactivated Polio Vaccine.	
	A. Anaphylaxis or anaphylactic shock	24 hours
	B. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed	Not applicable

(b) Qualifications and aids to interpretation

(1) A shock-collapse or a hypotonic-hyporesponsive collapse may be evidenced by indicia or symptoms such as decrease or loss of muscle tone, paralysis (partial or complete, hemiplegia or hemiparesis, loss of color or turning pale white or blue, unresponsiveness to environmental stimuli, depression of consciousness, loss of consciousness, prolonged sleeping with difficulty arousing, or cardiovascular or respiratory arrest.

(2) A petitioner may be considered to have suffered a residual seizure disorder if the petitioner did not suffer a seizure or convulsion unaccompanied by fever or accompanied by a fever of less than 102 degrees Fahrenheit before the first seizure or convulsion after the administration of the vaccine involved and if—

(A) in the case of a measles, mumps, or rubella vaccine or any combination of such vaccines, the first seizure or convulsion occurred within 15 days after administration of the vaccine and 2 or more seizures or convulsions occurred within 1 year after the administration of the vaccine which were unaccompanied by fever or accompanied by a fever of less than 102 degrees Fahrenheit, and

(B) in the case of any other vaccine, the first seizure or convulsion occurred within 3 days after administration of the vaccine and 2 or more seizures or convulsions occurred within 1 year after the administration of the vaccine which were unaccompanied by fever or accompanied by a fever of less than 102 degrees Fahrenheit.

(3)(A) The term "encephalopathy" means any significant acquired abnormality of, or injury to, or impairment of function of the brain. Among the frequent manifestations of encephalopathy are focal and diffuse neurologic signs, increased intracranial pressure, or changes lasting at least 6 hours in level of consciousness, with or without convulsions. The neurological signs and symptoms of encephalopathy may be temporary with complete recovery, or may result in various degrees of permanent impairment. Signs and symptoms such as high pitched and unusual screaming, persistent unconsolable crying, and bulging fontanel are compatible with an encephalopathy, but in and of themselves are not conclusive evidence of encephalopathy. Encephalopathy usually can be documented by slow wave activity on an electroencephalogram.

(B) If in a proceeding on a petition it is shown by a preponderance of the evidence that an encephalopathy was caused by infection, toxins, trauma, or metabolic disturbances the encephalopathy shall not be considered to be a condition set forth in the table. If at the time a judgment is entered on a petition filed under section 300aa–11(b) of this title for a vaccine-related injury or death it is not possible to determine the cause, by a preponderance of the evidence, of an encephalopathy, the encephalopathy shall be considered to be a condition set forth in the table. In determining whether or not an encephalopathy is a condition set forth in the table, the court shall consider the entire medical record.

(4) For purposes of paragraphs (2) and (3), the terms "seizure" and "convulsion" include grand mal, petit mal, absence, myoclonic, tonic-clonic, and focal motor seizures and signs. If a provision of the table to which paragraph (1), (2), (3), or (4) applies is revised under subsection (c) or (d) of this section, such paragraph shall not apply to such provision after the effective date of the revision unless the revision specifies that such paragraph is to continue to apply.

(c) Administrative revision of the table

(1) The Secretary may promulgate regulations to modify in accordance with paragraph (3) the Vaccine Injury Table. In promulgating such regulations, the Secretary shall provide for notice and opportunity for a public hearing and at least 180 days of public comment.

(2) Any person (including the Advisory Commission on Childhood Vaccines) may petition the Secretary to propose regulations to amend the Vaccine Injury Table. Unless clearly frivolous, or initiated by the Commission, any such petition shall be referred to the Commission for its recommendations. Following—

(A) receipt of any recommendation of the Commission, or

(B) 180 days after the date of the referral to the Commission

whichever occurs first, the Secretary shall conduct a rulemaking proceeding on the matters proposed in the petition or publish in the Federal Register a statement of reasons for not conducting such proceeding.

(3) A modification of the Vaccine Injury Table under paragraph (1) may add to, or delete from, the list of injuries, disabilities, illnesses, conditions, and deaths for which compensation may be provided or may change the time periods for the first symptom or manifestation of the onset or the significant aggravation of any such injury, disability, illness, condition, or death.

(4) Any modification under paragraph (1) of the Vaccine Injury Table shall apply only with respect to petitions for compensation under the Program which are filed after the effective date of such regulation.

(d) Role of commission

Except with respect to a regulation recommended by the Advisory Commission on Childhood Vaccines, the Secretary may not propose a regulation under subsection (c) of this section or any revision thereof, unless the Secretary has first provided to the Commission a copy of the proposed regulation or revision, requested recommendations and comments by the Commission, and afforded the Commission at least 90 days to make such recommendations.

(e) Recommendation

The Secretary may recommend to Congress revisions of the table to change the vaccines covered by the table.

(July 1, 1944, c. 373, Title XXI, § 2114, as added Nov. 14, 1986, Pub.L. 99-660, Title III, § 311(a), 100 Stat. 3764.)

Legislative History. For legislative history and purpose of Pub.L. 99-660, see 1986 U.S. Code Cong. and Adm. News, p. 6287.

§ 300aa-15. Compensation

(a) General rule

Compensation awarded under the Program to a petitioner under section 300aa-11 of this title for a vaccine-related injury or death associated with the administration of a vaccine after the effective date of this part shall include the following:

(1)(A) Actual unreimbursable expenses incurred from the date of the judgment awarding such expenses and reasonable projected unreimbursable expenses which—

(i) result from the vaccine-related injury for which the petitioner seeks compensation,

(ii) have been or will be incurred by or on behalf of the person who suffered such injury, and

(iii)(I) have been or will be for diagnosis and medical or other remedial care determined to be reasonably necessary, or

(II) have been or will be for rehabilitation, developmental evaluation, special education, vocational training and placement, case management services, counseling, emotional or behavioral therapy, residential and custodial care and service expenses, special equipment, related travel expenses, and facilities determined to be reasonably necessary.

The amount of unreimbursable expenses which may be recovered under this subparagraph shall be limited to the amount in excess of the amount set forth in section 300aa-11(e)(1)(D)(ii) of this title.

(B) Subject to section 300aa-16(a)(2) of this title, actual unreimbursable expenses incurred before the date of the judgment awarding such expenses which—

(i) resulted from the vaccine-related injury for which the petitioner seeks compensation,

(ii) were incurred by or on behalf of the person who suffered such injury,

(iii) were for diagnosis, medical or other remedial care, rehabilitation, developmental evaluation, special education, vocational training and placement, case management services, counseling, emotional or behavioral therapy, residential and custodial care and service expenses, special equipment, related travel expenses, and facilities determined to be reasonably necessary.

The amount of unreimbursable expenses which may be recovered under this subparagraph shall be limited to the amount in excess of the amount set forth in section 300aa-11(e)(1)(D)(ii) of this title.

(2) In the event of a vaccine-related death, an award of $250,000 for the estate of the deceased.

(3)(A) In the case of any person who has sustained a vaccine-related injury after attaining the age of 18 and whose earning capacity is or has been impaired by reason of such person's vaccine-related injury for which compensation is to be awarded, compensation for actual and anticipated loss of earnings determined in accordance with generally recognized actuarial principles and projections.

(B) In the case of any person who has sustained a vaccine-related injury before attaining the age of 18 and whose earning capacity is or has been impaired by reason of such person's vaccine-related injury for which compensation is to be awarded and whose vaccine-related injury is of sufficient severity to permit reasonable anticipation that such person is likely to suffer impaired earning capacity at 18 and beyond, compensation after attaining the age of 18 for loss of earnings determined on the basis of the average gross weekly earnings of workers in the private, non-farm sector, less appropriate taxes and the average cost of a health insurance policy, as determined by the Secretary.

(4) For actual and projected pain and suffering and emotional distress from the vaccine-related injury, an award not to exceed $250,000.

Payments for projected expenses shall be paid on a periodic basis (but no payment may be made for a period in excess of 1 year). Payments for pain and suffering and emotional distress and incurred expenses may be paid in a lump sum.

(b) Vaccines administered before the effective date

Compensation awarded under the Program to a petitioner under section 300aa-11 of this title for a vaccine-related injury or death associated with the administration of a vaccine before the effective date of this part shall only include the compensation described in paragraphs (1)(A) and (2) of subsection (a) of this section.

(c) Residential and custodial care and service

The amount of any compensation for residential and custodial care and service expenses under subsection (a)(1) of this section shall be sufficient to enable the compensated person to remain living at home.

(d) Types of compensation prohibited

Compensation awarded under the Program may not include the following:

(1) Punitive or exemplary damages.

(2) Except with respect to compensation payments under paragraphs (2) and (3) of subsection (a) of this section, compensation for other than the health, education, or welfare of the person who suffered the vaccine-related injury with respect to which the compensation is paid.

(e) Attorneys' fees

(1) The judgment of a court on a petition filed under section 300aa-11 of this title awarding compensation shall include an amount to cover—

(A) reasonable attorneys' fees, and

(B) other costs,

incurred in any proceeding on such petition. If the judgment of a court on such a petition does not award compensation, the court may include in the judgment an amount to cover petitioner's reasonable attorneys' fees and other costs incurred in any proceeding on such petition if the court determines that the civil action was brought in good faith and there was a reasonable basis for the claim for which the civil action was brought

(2) If the petitioner, before the effective date of this part, filed a civil action for damages for any vaccine-related injury or death for which compensation may be awarded under the Program, and elected under section 300aa-11(a)(4) of this title to withdraw such action and to file a petition for compensation under the Program, the judgment of the court on such petition may include an amount limited to the costs and expenses incurred by the petitioner and the attorney of the petitioner before the effective date of this part in preparing, filing, and prosecuting such civil action (including the reasonable value of the attorney's time if the civil action was filed under contingent fee arrangements).

(3) No attorney may charge any fee for services in connection with a petition filed under section 300aa-11 of this title which is in addition to any amount included under paragraph (1) in a judgment on such petition.

(f) Payment of compensation

(1) Except as provided in paragraph (2), no compensation may be paid until an election has been made, or has been deemed to have been made, under section 300aa-21(a) of this title to receive compensation.

(2) Compensation described in subsection (a)(1)(A)(iii) of this section shall be paid from the date of the judgment of the district court of the United States under section 300aa-12 of this title awarding the compensation. Such compensation may not be paid after an election under section 300aa-21(b) of this title to file a civil action for damages for the vaccine-related injury or death for which such compensation was awarded.

(3) Payments of compensation shall be exempt from reduction under any order issued under part C of the Balanced Budget and Emergency Deficit Control Act of 1985.

(f) Program not primarily liable.

Payment of compensation under the Program shall not be made for any item or service to the extent that payment has been made, or can reasonably be expected to be made, with respect to such item or service (1) under any State compensation program, under an insurance policy, or under any Federal or State health benefits program, or (2) by an entity which provides health services on a prepaid basis.

(g) Liability of health insurance carriers, prepaid health plans, and benefit providers

No policy of health insurance may make payment of benefits under the policy secondary to the payment of compensation under the Program and—

(1) no State, and

(2) no entity which provides health services on a prepaid basis or provides health benefits,

may make the provision of health services or health benefits secondary to the payment of compensation under the Program.

(July 1, 1944, c. 373, Title XXI, § 2115, as added Nov. 14, 1986, Pub.L. 99-660, Title III, § 311(a), 100 Stat. 3767.)

References in Text. The effective date of this part, referred to in subsec. (a), (b), (e)(2), is the effective date of part II of subchapter XIX of this chapter which shall take effect on the effective date of a tax enacted after Nov. 14, 1986 to provide funds for compensation under such part 2, see section 323 of Pub.L. 99-660, set out as an Effective Date note under section 300aa-1 of this title.

Legislative History. For legislative history and purpose of Pub.L. 99-660, see 1986 U.S. Code Cong. and Adm. News, p. 6287.

§ 300aa-16. Limitations of actions

(a) General rule

In the case of—

(1) a vaccine set forth in the Vaccine Injury Table which is administered before the effective date of this subchapter, if a vaccine-related injury or death occurred as a result of the administration of such vaccine, no petition may be filed for compensation under the Program for such injury or death after the

(2) a vaccine set forth in the Vaccine Injury Table which is administered after the effective date of this subchapter, if a vaccine-related injury occurred as a result of the administration of such vaccine, no petition may be filed for compensation under the Program for such injury after the expiration of 36 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of such injury, and

(3) a vaccine set forth in the Vaccine Injury Table which is administered after the effective date of this subchapter, if a death occurred as a result of the administration of such vaccine, no petition may be filed for compensation under the Program for such death after the expiration of 24 months from the date of the death and no such petition may be filed more than 48 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of the injury from which the death resulted.

(b) Effect of revised table

If at any time the Vaccine Injury Table is revised and the effect of such revision is to permit an individual who was not, before such revision, eligible to seek compensation under the Program, such person may file a petition for such compensation not later than 2 years after the effective date of the revision, except that no compensation may be provided under the Program with respect to a vaccine-related injury or death covered under the revision of the table if—

(1) the vaccine-related death occurred more than 8 years before the date of the revision of the table, or

(2) the vaccine-related injury occurred more than 8 years before the date of the revision of the table.

(c) State limitations of actions

If a petition is filed under section 300aa-11(b) of this title for a vaccine-related injury or death, limitations of actions under State law shall be stayed with respect to a civil action brought for such injury or death for the period beginning on the date the petition is filed and ending on the date a final judgment is entered on the petition.

(July 1, 1944, c. 373, Title XXI, § 2116, as added Nov. 14, 1986, Pub.L. 99-660, Title III, § 311(a), 100 Stat. 3769.)

References in Text. For effective date of this subchapter, referred to in subsec. (a)(1), (2), (3), see section 323 of Pub.L. 99-660, set out as an Effective Date note under section 300aa-1 of this title.

Legislative History. For legislative history and purpose of Pub.L. 99-660, see 1986 U.S. Code Cong. and Adm. News, p. 6287.

§ 300aa-17. Subrogation

(a) General rule

(1) Upon payment of compensation to any petitioner under the Program, the trust fund which has been established to provide such compensation shall be subrogated to all rights of the petitioner with respect to the vaccine-related injury or death for which compensation was paid, except that the trust fund may not recover under such rights an amount greater than the amount of compensation paid to the petitioner.

(2) In any case in which it deems such action appropriate, a district court of the United States may, after entry of a final judgment providing for compensation to be paid under section 300aa-15 of this title for a vaccine-related injury or death, refer the record of such proceeding to the Secretary and the Attorney General with such recommendation as the court deems appropriate with respect to the investigation or commencement of a civil action by the Secretary under paragraph (1).

(b) Disposition of amounts recovered

Amounts recovered under subsection (a) of this section shall be collected on behalf of, and deposited in, the trust fund which has been established to provide compensation under the Program.

(July 1, 1944, c. 373, Title XXI, § 2117, as added Nov. 14, 1986, Pub.L. 99-660, Title III, § 311(a), 100 Stat. 3770.)

Legislative History. For legislative history and purpose of Pub.L. 99–660, see 1986 U.S. Code Cong. and Adm. News, p. 6287.

§ 300aa–18. Increase for inflation

The compensation under subsections (a)(2) and (a)(4) of section 300aa–15 of this title the civil penalty under section 300aa–27(b) of this title shall, effective December 1 of each year beginning 1 year after the effective date of this subchapter, be increased by the percent change in the Consumer Price Index for the base quarter of such year over the Consumer Price Index for the base quarter of the preceding year, adjusted to the nearest 1/10 of 1 percent. For purposes of this section, the term "base quarter", as used with respect to a year, means the calendar quarter ending on September 30 of such year and the price index for a base quarter is the arithmetical mean of such index for the 3 months comprising such quarter.

(July 1, 1944, c. 373, Title XXI, § 2118, as added Nov. 14, 1986, Pub.L. 99–660, Title III, § 311(a), 100 Stat. 3771.)

References in Text. For the effective date of this subchapter, referred to in text, see section 323 of Pub.L. 99–660, set out as an Effective Date note under section 300aa–1 of this title.

Legislative History. For legislative history and purpose of Pub.L. 99–660, see 1986 U.S. Code Cong. and Adm. News, p. 6287.)

§ 300aa–19. Advisory Commission on Childhood Vaccines

(a) Establishment

There is established the Advisory Commission on Childhood Vaccines. The Commission shall be composed of:

(1) Nine members appointed by the Secretary as follows:

(A) Three members who are health professionals, who are not employees of the United States, and who have expertise in the health care of children, the epidemiology, etiology, and prevention of childhood diseases, and the adverse reactions associated with vaccines, of whom at least two shall be pediatricians.

(B) Three members from the general public, of whom at least two shall be legal representatives of children who have suffered a vaccine-related injury or death.

(C) Three members who are attorneys, of whom at least one shall be an attorney whose specialty includes representation of persons who have suffered a vaccine-related injury or death and of whom one shall be an attorney whose specialty includes representation of vaccine manufacturers.

(2) The Director of the National Institutes of Health, the Assistant Secretary for Health, the Director of the Centers for Disease Control, and the Commissioner of Food and Drugs (or the designees of such officials), each of whom shall be a nonvoting ex officio member.

The Secretary shall select members of the Commission within 90 days of the effective date of this part. The members of the Commission shall select a Chair from among the members.

(b) Term of office

Appointed members of the Commission shall be appointed for a term of office of 3 years, except that of the members first appointed, 3 shall be appointed for a term of 1 year, 3 shall be appointed for a term of 2 years, and 3 shall be appointed for a term of 3 years, as determined by the Secretary.

(c) Meetings

The Commission shall first meet within 60 days after all members of the Commission are appointed, and thereafter shall meet not less often than four times per year and at the call of the chair. A quorum for purposes of a meeting is 5. A decision at a meeting is to be made by a ballot of a majority of the voting members of the

(d) Compensation

Members of the Commission who are officers or employees of the Federal Government shall serve as members of the Commission without compensation in addition to that received in their regular public employment. Members of the Commission who are not officers or employees of the Federal Government shall be compensated at a rate not to exceed the daily equivalent of the rate in effect for grade GS–18 of the General Schedule for each day (including traveltime) they are engaged in the performance of their duties as members of the Commission. All members, while so serving away from their homes or regular places of business, may be allowed travel expenses, including per diem in lieu of subsistence, in the same manner as such expenses are authorized by section 5703, Title 5, for employees serving intermittently.

(e) Staff

The Secretary shall provide the Commission with such professional and clerical staff, such information, and the services of such consultants as may be necessary to assist the Commission in carrying out effectively its functions under this section.

(f) Functions

The Commission shall—

(1) advise the Secretary on the implementation of the Program,

(2) on its own initiative or as the result of the filing of a petition, recommend changes in the Vaccine Injury Table,

(3) advise the Secretary in implementing the Secretary's responsibilities under section 300aa–27 of this title regarding the need for childhood vaccination products that result in fewer or no significant adverse reactions,

(4) survey Federal, State, and local programs and activities relating to the gathering of information on injuries associated with the administration of childhood vaccines, including the adverse reaction reporting requirements of section 300aa–25(b) of this title, and advise the Secretary on means to obtain, compile, publish, and use credible data related to the frequency and severity of adverse reactions associated with childhood vaccines, and

(5) recommend to the Director of the National Vaccine Program research related to vaccine injuries which should be conducted to carry out this part.

(July 1, 1944, c. 373, Title XXI, § 2119, as added Nov. 14, 1986, Pub.L. 99–660, Title III, § 311(a), 100 Stat. 3771.)

References in Text. The effective date of this part, referred to in subsec. (a) is the effective date of part II of subchapter XIX of this chapter which shall take effect on the effective date of a tax enacted after Nov. 14, 1986 to provide funds for compensation paid under such part 2, see section 323 of Pub.L. 99–660, set out as an Effective Date note under section 300aa–1 of this title.

Legislative History. For legislative history and purpose of Pub.L. 99–660, see 1986 U.S.Code Cong. and Adm.News, p. 6287.

Subpart B—Additional Remedies

§ 300aa–21. Authority to bring actions

(a) Election

After the judgment of a district court of the United States under section 300aa–11 of this title on a petition filed for compensation under the Program for a vaccine-related injury or death has become final, the person who filed the petition shall file with the court—

(1) if the judgment awarded compensation, an election in writing to receive the compensation or to file a civil action for damages for such injury or death, or

(2) if the judgment did not award compensation, an election in writing to accept the judgment or to file a civil action for damages for such injury or death.

An election shall be filed under this subsection not later than 90 days after the date of the entry of the court's judgment with respect to which the election is to be made. If a person required to file an election with a court under this subsection does not file the election within the time prescribed for filing the election, such person shall be deemed to have filed an election to accept the judgment of the court. If a person elects to receive compensation under a judgment of a court or is deemed to have

accepted the judgment of a court, such person may not bring or maintain a civil action for damages against a vaccine manufacturer for the vaccine-related injury or death for which the judgment was entered.

(b) Limitations of actions

A civil action for damages arising from a vaccine-related injury or death for which a petition was filed under section 300aa–11 of this title shall, except as provided in section 300aa–16(b) of this title, be brought within the period prescribed by limitations of actions under State law applicable to such civil action.

(July 1, 1944, c. 373, Title XXI, § 2121, as added Nov. 14, 1986, Pub.L. 99–660, Title III, § 311(a), 100 Stat. 3772.)

Legislative History. For legislative history and purpose of Pub.L. 99–660, see 1986 U.S.Code Cong. and Adm.News, p. 6287.

§ 300aa–22. Standards of responsibility

(a) General rule

Except as provided in subsections (b), (c), and (e) of this section State law shall apply to a civil action brought for damages for a vaccine-related injury or death.

(b) Unavoidable adverse side effects; warnings

(1) No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after the effective date of this part if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings.

(2) For purposes of paragraph (1), a vaccine shall be presumed to be accompanied by proper directions and warnings if the vaccine manufacturer shows that it complied in all material respects with all requirements under the Federal Food, Drug, and Cosmetic Act and section 262 of this title (including regulations issued under such provisions) applicable to the vaccine and related to vaccine-related injury or death for which the civil action was brought unless the plaintiff shows—

(A) that the manufacturer engaged in the conduct set forth in subparagraph (A) or (B) of section 300aa–23(d)(2) of this title, or

(B) by clear and convincing evidence that the manufacturer failed to exercise due care notwithstanding its compliance with such Act and section (and regulations issued under such provisions).

(c) Direct warnings

No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after the effective date of this part solely due to the manufacturer's failure to provide direct warnings to the injured party (or the injured party's legal representative) of the potential dangers resulting from the administration of the vaccine manufactured by the manufacturer.

(d) Construction

The standards of responsibility prescribed by this section are not to be construed as authorizing a person who brought a civil action for damages against a vaccine manufacturer for a vaccine-related injury or death in which damages were denied or which was dismissed with prejudice to bring a new civil action against such manufacturer for such injury or death.

(e) Preemption

No State may establish or enforce a law which prohibits an individual from bringing a civil action against a vaccine manufacturer for damages for a vaccine-related injury or death if such civil action is not barred by this part.

(July 1, 1944, c. 373, Title XXI, § 2122, as added Nov. 14, 1986, Pub.L. 99–660, Title III, § 311(a), 100 Stat. 3773.)

References in Text. The effective date of this part, referred to in subsecs. (b)(1) and (c), is the effective date of part II of subchapter XIX of this chapter which shall take effect on the effective date of a tax enacted after Nov. 14, 1986 to provide funds for compensation paid under such part 2, see section 323 of Pub.L. 99–660, set out as an Effective Date note under section 300aa–1 of this title.

Legislative History. For legislative history and purpose of Pub.L. 99–660, see 1986 U.S.Code Cong. and Adm.News, p. 6287.

§ 300aa–23. Trial

(a) General rule

A civil action against a vaccine manufacturer for damages for a vaccine-related injury or death associated with the administration of a vaccine after the effective date of this part which is not barred by section 300aa–11(a)(2) of this title shall be tried in three stages.

(b) Liability

The first stage of such a civil action shall be held to determine if a vaccine manufacturer is liable under section 300aa–22 of this title.

(c) General damages

The second stage of such a civil action shall be held to determine the amount of damages (other than punitive damages) a vaccine manufacturer found to be liable under section 300aa–22 of this title shall be required to pay.

(d) Punitive damages

(1) If sought by the plaintiff, the third stage of such an action shall be held to determine the amount of punitive damages a vaccine manufacturer found to be liable under section 300aa–22 of this title shall be required to pay.

(2) If in such an action the manufacturer shows that it complied, in all material respects, with all requirements under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act applicable to the vaccine and related to the vaccine injury or death with respect to which the action was brought, the manufacturer shall not be held liable for punitive damages unless the manufacturer engaged in—

(A) fraud or intentional and wrongful withholding of information from the Secretary during any phase of a proceeding for approval of the vaccine under section 262 of this title,

(B) intentional and wrongful withholding of information relating to the safety or efficacy of the vaccine after its approval, or

(C) other criminal or illegal activity relating to the safety and effectiveness of vaccines,

which activity related to the vaccine-related injury or death for which the civil action was brought.

(e) Evidence

In any stage of a civil action, the Vaccine Injury Table, any finding of a district court of the United States or a master appointed by such court in a proceeding on a petition filed under section 300aa–11 of this title and the final judgment of a district court of the United States on such a petition shall not be admissible.

(July 1, 1944, c. 373, Title XXI, § 2123, as added Nov. 14, 1986, Pub.L. 99–660, Title III, § 311(a), 100 Stat. 3774.)

References in Text. The effective date of this part, referred to in subsec. (a), is the effective date of part II of subchapter XIX of this chapter which shall take effect on the effective date of a tax enacted after Nov. 14, 1986 to provide funds for compensation paid under such part 2, see section 323 of Pub.L. 99–660, set out as an Effective Date note under section 300aa–1 of this title.

Legislative History. For legislative history and purpose of Pub.L. 99–660, see 1986 U.S.Code Cong. and Adm.News, p. 6287.

PART C—ASSURING A SAFER CHILDHOOD VACCINATION PROGRAM IN THE UNITED STATES

§ 300aa–25. Recording and reporting of information

(a) General rule

Each health care provider who administers a vaccine set forth in the Vaccine Injury Table to any person shall record, or ensure that there is recorded, in such person's permanent medical record (or in a permanent office log or file to which a legal representative shall have access upon request) with respect to each such vaccine—

(1) the date of administration of the vaccine,

(2) the vaccine manufacturer and lot number of the vaccine,

(3) the name and address and, if appropriate, the title of the health care provider administering the vaccine, and

(4) any other identifying information on the vaccine required pursuant to regulations promulgated by the Secretary.

(b) Reporting

(1) Each health care provider and vaccine manufacturer shall report to the Secretary—

(A) the occurrence of any event set forth in the Vaccine Injury Table, including the events set forth in section 300aa–14(b) of this title which occur within 7 days of the administration of any vaccine set forth in the Table or within such longer period as is specified in the Table or section,

(B) the occurrence of any contraindicating reaction to a vaccine which is specified in the manufacturer's package insert, and

(C) such other matters as the Secretary may by regulation require.

Reports of the matters referred to in subparagraphs (A) and (B) shall be made beginning 90 days after the effective date of this part. The Secretary shall publish in the Federal Register as soon as practicable after such date a notice of the reporting requirement.

(2) A report under paragraph (1) respecting a vaccine shall include the time periods after the administration of such vaccine within which vaccine-related illnesses, disabilities, injuries, or conditions, the symptoms and manifestations of such illnesses, disabilities, injuries, or conditions, or deaths occur, and the manufacturer and lot number of the vaccine.

(3) The Secretary shall issue the regulations referred to in paragraph (1)(C) within 180 days of the effective date of this part.

(c) Release of information

(1) Information which is in the possession of the Federal Government and State and local governments under this section and which may identify an individual shall not be made available under section 552 of Title 5, or otherwise, to any person except—

(A) the person who received the vaccine, or

(B) the legal representative of such person.

(2) For purposes of paragraph (1), the term "information which may identify an individual" shall be limited to the name, street address, and telephone number of the person who received the vaccine and of that person's legal representative and the medical records of such person relating to the administration of the vaccine, and shall not include the locality and State of vaccine administration, the name of the health care provider who administered the vaccine, the date of the vaccination, or information concerning any reported illness, disability, injury, or condition resulting from the administration of the vaccine, any symptom or manifestation of such illness, disability, injury, or condition, or death resulting from the administration of the vaccine.

(3) Except as provided in paragraph (1), all information reported under this section shall be available to the public.

(July 1, 1944, c. 373, Title XXI, § 2125, as added Nov. 14, 1986, Pub.L. 99–660, Title III, § 311(a),

References in Text. The effective date of this part, referred to in subsec. (b)(1), (2), is the effective date of part II of subchapter XIX of this chapter which shall become effective on the effective date of a tax enacted after Nov. 14, 1986 to provide funds for compensation paid under such part 2, see section 323 of Pub.L. 99–660, set out as an Effective Date note under section 300aa–1 of this title.

Legislative History. For legislative history and purpose of Pub.L. 99–660, see 1986 U.S.Code Cong. and Adm.News, p. 6287.

§ 300aa–26. Vaccine information

(a) General rule

Not later than 1 year after the effective date of this part, the Secretary shall develop and disseminate vaccine information materials for distribution by health care providers to the legal representatives of any child receiving a vaccine set forth in the Vaccine Injury Table. Such materials shall be published in the Federal Register and may be revised.

(b) Development and revision of materials

Such materials shall be developed or revised by rule—

(1) after notice to the public, opportunity for a public hearing, and 90 days of comment thereon, and

(2) in consultation with the Advisory Commission on Childhood Vaccines, appropriate health care providers and parent organizations, the Centers for Disease Control, and the Food and Drug Administration.

(c) Information requirements

The information in such materials shall be presented in understandable terms and shall include—

(1) the frequency, severity, and potential long-term effects of the disease to be prevented by the vaccine,

(2) the symptoms or reactions to the vaccine which, if they occur, should be brought to the immediate attention of the health care provider,

(3) precautionary measures legal representatives should take to reduce the risk of any major adverse reactions to the vaccine that may occur,

(4) early warning signs or symptoms to which legal representatives should be alert as possible precursors to such major adverse reactions,

(5) a description of the manner in which legal representatives should monitor such major adverse reactions, including a form on which reactions can be recorded to assist legal representatives in reporting information to appropriate authorities,

(6) a specification of when, how, and to whom legal representatives should report any major adverse reaction,

(7) the contraindications to (and bases for delay of) the administration of the vaccine,

(8) an identification of the groups, categories, or characteristics of potential recipients of the vaccine who may be at significantly higher risk of major adverse reaction to the vaccine than the general population,

(9) a summary of relevant State and Federal laws concerning the vaccine, including information on—

(A) the number of vaccinations required for school attendance and the schedule recommended for such vaccinations, and

(B) the availability of the Program, and

(10) such other relevant information as may be determined by the Secretary.

(d) Health care provider duties

On and after a date determined by the Secretary which is—

(1) after the Secretary develops the information materials required by subsection (a), and

(2) not later than 6 months after the date such materials are published in the Federal Register,

each health care provider who administers a vaccine set forth in the Vaccine Injury Table shall provide to the legal representatives of any child to whom such provider intends to administer such vaccine a copy of the information materials developed

pursuant to subsection (a) of this section, or other written information which meets the requirements of this section. Such materials or other information shall be provided prior to the administration of such vaccine.

(July 1, 1944, c. 373, Title XXI, § 2126, as added Nov. 14, 1986, Pub.L. 99–660, Title III, § 311(a), 100 Stat. 3775.)

References in Text. The effective date of this part, referred to in subsec. (a), is the effective date of part 2 of subchapter XIX of this chapter which shall become effective on the effective date of a tax enacted after Nov. 14, 1986 to provide funds for compensation paid under such part 2, see section 323 of Pub.L. 99–660, set out as an Effective Date note under section 300aa–1 of this title.

Legislative History. For legislative history and purpose of Pub.L. 99–660, see 1986 U.S. Code Cong. and Adm. News, p. 6287.

§ 300aa–27. Mandate for safer childhood vaccines

(a) General rule

In the administration of this part and other pertinent laws under the jurisdiction of the Secretary, the Secretary shall—

(1) promote the development of childhood vaccines that result in fewer and less serious adverse reactions than those vaccines on the market on the effective date of this part and promote the refinement of such vaccines, and

(2) make or assure improvements in, and otherwise use the authorities of the Secretary with respect to, the licensing, manufacturing, processing, testing, labeling, warning, use instructions, distribution, storage, administration, field surveillance, adverse reaction reporting, and recall of reactogenic lots or batches, of vaccines, and research on vaccines, in order to reduce the risks of adverse reactions to vaccines.

(b) Report

Within 2 years after the effective date of this part, and periodically thereafter, the Secretary shall prepare and transmit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report describing the actions taken pursuant to subsection (a) of this section during the preceding 2-year period.

(July 1, 1944, c. 373, Title XXI, § 2127, as added Nov. 14, 1986, Pub.L. 99–660, Title III, § 311(a), 100 Stat. 3777.

References in Text. The effective date of this part, referred to in subsecs. (a) and (b), is the effective date of part 2 of subchapter XIX of this chapter which shall take effect on the effective date of a tax enacted after Nov. 14, 1986 to provide funds for compensation paid under such part 2, see section 323 of Pub.L. 99–660, set out as an Effective Date note under section 300aa–1 of this title.

Legislative History. For legislative history and purpose of Pub.L. 99–660, see 1986 U.S. Code Cong. and Adm. News, p. 6287.

§ 300aa–28. Manufacturer recordkeeping and reporting

(a) General rule

Each vaccine manufacturer of a vaccine set forth in the Vaccine Injury Table or any other vaccine the administration of which is mandated by the law or regulations of any State, shall, with respect to each batch, lot, or other quantity manufactured or licensed after the effective date of this part—

(1) prepare and maintain records documenting the history of the manufacturing, processing, testing, repooling, and reworking of each batch, lot, or other quantity of such vaccine, including the identification of any significant problems encountered in the production, testing, or handling of such batch, lot, or other quantity,

(2) if a safety test on such batch, lot, or other quantity indicates a potential imminent or substantial public health hazard is presented, report to the Secretary within 24 hours of such safety test which the manufacturer (or manufacturer's representative) conducted, including the date of the test, the type of vaccine tested, the identity of the batch, lot, or other quantity tested, whether the batch, lot, or other quantity tested is the product of repooling or reworking of previous [illegible] the identity of the previous batches,

lots, or other quantities which were repooled or reworked), the complete test results, and the name and address of the person responsible for conducting the test,

(3) include with each such report a certification signed by a responsible corporate official that such report is true and complete, and

(4) prepare, maintain, and upon request submit to the Secretary product distribution records for each such vaccine by batch, lot, or other quantity number.

(b) Sanction

Any vaccine manufacturer who intentionally destroys, alters, falsifies, or conceals any record or report required under paragraph (1) or (2) of subsection (a) shall—

(1) be subject to a civil penalty of up to $100,000 per occurrence, or

(2) be fined $50,000 or imprisoned for not more than 1 year, or both.

Such penalty shall apply to the person who intentionally destroyed, altered, falsified, or concealed such record or report, to the person who directed that such record or report be destroyed, altered, falsified, or concealed, and to the vaccine manufacturer for which such person is an agent, employee, or representative. Each act of destruction, alteration, falsification, or concealment shall be treated as a separate occurrence.

(July 1, 1944, c. 373, Title XXI, § 2128, as added Nov. 14, 1986, Pub.L. 99–660, Title III, § 311(a), 100 Stat. 3777.)

References in Text. The effective date of this part, referred to in subsec. (a), is the effective date of part 2 of subchapter XIX of this chapter which shall take effect on the effective date of a tax enacted after Nov. 14, 1986 to provide funds for compensation paid under such part 2, see section 323 of Pub.L. 99–660, set out as an Effective Date note under section 300aa–1 of this title.

Legislative History. For legislative history and purpose of Pub.L. 99–660, see 1986 U.S. Code Cong. Adm. News, p. 6287.

PART D—GENERAL PROVISIONS

§ 300aa–31. Citizen's actions

(a) General rule

Except as provided in subsection (b) of this section, any person may commence in a district court of the United States a civil action on such person's own behalf against the Secretary where there is alleged a failure of the Secretary to perform any act or duty under this part.

(b) Notice

No action may be commenced under subsection (a) of this section before the date which is 60 days after the person bringing the action has given written notice of intent to commence such action to the Secretary.

(c) Costs of litigation

The court, in issuing any final order in any action under this section, may award costs of litigation (including reasonable attorney and expert witness fees) to any party, whenever the court determines such award is appropriate.

(July 1, 1944, c. 373, Title XXI, § 2131, as added Nov. 14, 1986, Pub.L. 99–660, Title III, § 311(a), 100 Stat. 3778.)

Legislative History. For legislative history and purpose of Pub.L. 99–660, see 1986 U.S. Code Cong. and Adm. News, p. 6287.

§ 300aa–32. Judicial review

A petition for review of a regulation under this part may be filed in a court of appeals of the United States within 60 days from the date of the promulgation of the regulation or after such date if such petition is based solely on grounds arising after such 60th day.

(July 1, 1944, c. 373, Title XXI, § 2132, as added Nov. 14, 1986, Pub.L. 99–660, Title III, § 311(a), 100 Stat. 3778.)

Legislative History. For legislative history and purpose of Pub.L. 99–660, see 1986 U.S. Code Cong. and Adm. News, p. 6287.

§ 300aa–33. Definitions

For purposes of this part:

(1) The term "health care provider" means any licensed health care professional, organization, or institution, whether public or private (including Federal, State, and local departments, agencies, and instrumentalities) under whose authority a vaccine set forth in the Vaccine Injury Table is administered.

(2) The term "legal representative" means a parent or an individual who qualifies as a legal guardian under State law.

(3) The term "manufacturer" means any corporation, organization, or institution, whether public or private (including Federal, State, and local departments, agencies, and instrumentalities), which manufactures, imports, processes, or distributes under its label any vaccine set forth in the Vaccine Injury Table, except that, for purposes of section 300aa–28 of this title, such term shall include the manufacturer of any other vaccine covered by that section. The term "manufacture" means to manufacture, import, process, or distribute a vaccine.

(4) The term "significant aggravation" means any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health.

(5) The term "vaccine-related injury or death" means an illness, injury, condition, or death associated with one or more of the vaccines set forth in the Vaccine Injury Table, except that the term does not include an illness, injury, condition, or death associated with an adulterant or contaminant intentionally added to such a vaccine.

(6)(A) The term "Advisory Commission on Childhood Vaccines" means the Commission established under section 300aa–19 of this title.

(B) The term "Vaccine Injury Table" means the table set out in section 300aa–14 of this title.

(July 1, 1944, c. 373, Title XXI, § 2133, as added Nov. 14, 1986, Pub.L. 99–660, Title III, § 311(a), 100 Stat. 3778.)

Legislative History. For legislative history and purpose of Pub.L. 99–660, see 1986 U.S. Code Cong. and Adm. News, p. 6287.

SUBCHAPTER XX—REQUIREMENTS FOR CERTAIN GROUP HEALTH PLANS FOR CERTAIN STATE AND LOCAL EMPLOYEES

§ 300bb–1. State and local governmental group health plans must provide continuation coverage to certain individuals

(a) In general

In accordance with regulations which the Secretary shall prescribe, each group health plan that is maintained by any State that receives funds under this chapter, by any political subdivision of such a State, or by any agency or instrumentality of such a State or political subdivision, shall provide, in accordance with this subchapter, that each qualified beneficiary who would lose coverage under the plan as a result of a qualifying event is entitled, under the plan, to elect, within the election period, continuation coverage under the plan.

(b) Exception for certain plans

Subsection (a) of this section shall not apply to—

(1) any group health plan for any calendar year if all employers maintaining such plan normally employed fewer than 20 employees on a typical business day during the preceding calendar year, or

(2) any group health plan maintained for employees by the government of the District of Columbia or any territory or possession of the United States or any

Under regulations, rules similar to the rules of subsections (a) and (b) of section 52 of Title 26 (relating to employers under common control) shall apply for purposes of paragraph (1).

(July 1, 1944, c. 373, Title XXII, § 2201, as added Apr. 7, 1986, Pub.L. 99–272, Title X, § 10003(a), 100 Stat. 232.)

Effective Date. Section 10003(b) of Pub.L. 99–272 provided that:

"(1) General rule.—The amendments made by this section [enacting this subchapter and enacting a provision set out as a note under section 300bb–7 of this title] shall apply to plan years beginning on or after July 1, 1986.

"(2) Special rule for collective bargaining agreements.—In the case of a group health plan maintained pursuant to one or more collective bargaining agreements between employee representatives and one or more employers ratified before the date of the enactment of this Act [Apr. 7, 1986], the amendments made by this section shall not apply to plan years beginning before the later of—

"(A) the date on which the last of the collective bargaining agreements relating to the plan terminates (determined without regard to any extension thereof agreed to after the date of the enactment of this Act) [Apr. 7, 1986], or

"(B) January 1, 1987.

For purposes of subparagraph (A), any plan amendment made pursuant to a collective bargaining agreement relating to the plan which amends the plan solely to conform to any requirement added by this section shall not be treated as a termination of such collective bargaining agreement."

Legislative History. For legislative history and purpose of Pub.L. 99–272, see 1986 U.S.Code Cong. and Adm.News, p. 42.

§ 300bb–2. Continuation coverage

For purposes of section 300bb–1 of this title, the term "continuation coverage" means coverage under the plan which meets the following requirements:

(1) Type of benefit coverage

The coverage must consist of coverage which, as of the time the coverage is being provided, is identical to the coverage provided under the plan to similarly situated beneficiaries under the plan with respect to whom a qualifying event has not occurred. If coverage is modified under the plan for any group of similarly situated beneficiaries, such coverage shall also be modified in the same manner for all individuals who are qualified beneficiaries under the plan pursuant to this part in connection with such group.

(2) Period of coverage

The coverage must extend for at least the period beginning on the date of the qualifying event and ending not earlier than the earliest of the following:

(A) Maximum required period.—

(i) General rule for terminations and reduced hours.—In the case of a qualifying event described in section 300bb–3(2) of this title, except as provided in clause (ii), the date which is 18 months after the date of the qualifying event.

(ii) Special rule for multiple qualifying events.—If a qualifying event occurs during the 18 months after the date of a qualifying event described in section 300bb–3(2) of this title, the date which is 36 months after the date of the qualifying event described in section 300bb–3(2) of this title.

(iii) General rule for other qualifying events.—In the case of a qualifying event not described in section 300bb–3(2) of this title, the date which is 36 months after the date of the qualifying event.

(B) End of plan

The date on which the employer ceases to provide any group health plan to any employee.

(C) Failure to pay premium

The date on which coverage ceases under the plan by reason of a failure to make timely payment of any premium required under the plan with respect to the qualified beneficiary. The payment of any premium (other than any payment referred to in the last sentence of paragraph (3)) shall be considered to be timely if made within 30 days after the date due or within such longer period as applies to or under the plan.

ALASKA STATE LEGISLATURE
HOUSE OF REPRESENTATIVES
RESEARCH AGENCY

P.O. Box Y, State Capitol
Juneau, Alaska 99811-3100
Mail Stop 3100
(907) 465-3991

January 28, 1988

MEMORANDUM

TO: Representative Mike Navarre

FROM: Patricia Brawley
Legislative Analyst

RE: **Personal Exemption from Mandatory Immunization**
Research Request 88.075 (Supplemental Information)

You requested that we provide information about personal exemptions from mandatory immunization laws in Colorado, Wisconsin and Utah. Specifically, you wanted to know the following:

1. Historically, how did this personal exemption come about in those states, and what was the reason for the change in existing law?

2. What happened to the vaccination compliance rate as a result of these waivers? What is the current compliance rate?

3. What is the before and after frequency of the "serious seven" diseases in those states, and in what percentage of cases, if any, were the persons vaccinated?

4. Do parents have the opportunity to "pick and choose" which vaccinations their children will receive, or is it an "all or nothing" proposition?

The Center for Disease Control in Atlanta indicates that all states have mandatory immunization laws. The following exemptions have been incorporated into law: every state allows a medical exemption; every state, except Mississippi and West Virginia, allows a religious exemption; and 22 states allow a philosophical (personal) exemption. Responses to your specific questions concerning Colorado, Wisconsin and Utah follow.

COLORADO

According to Judy Canner, Immunization Program Director, Colorado Department of Health, the state's mandatory immunization law was in place by 1975. The original version covered only kindergartners, transfer students through grade 6, and child care facility enrollees. An amendment in 1978 extended coverage to all students in public schools and added the personal exemption. The push for inclusion of a personal exemption was based on the argument that the law was an infringement of personal rights. Colorado officials believe that the amendment would not have passed without the addition of the personal exemption.

The Colorado Department of Health does not consider the personal exemption to have significantly affected compliance rates. Statistics showing percentage of compliance and percentage of personal exemptions suggest, however, that the compliance rate is in a slight downward trend while the personal exemption rate is climbing.

School Year	Compliance Rate (%)	Personal Exemption Rate (%)
78-79	90	0.3
79-80	97.7	0.5
80-81	unavailable	unavailable
81-82	97.4	0.6
82-83	97.8	0.7
83-84	97.4	0.8
84-85	97.2	0.8
85-86	97.4	0.8
86-87	97.1	0.9

There is little correlation between the personal exemption and the frequency of disease outbreak. Frequency has continued to decline during the last decade, except in the case of pertussis (whooping cough), which has been on the increase. This is a reflection of the law rather than the exemption, however, because Colorado does not require immunization against pertussis. Colorado currently has a an outbreak of measles in a college community; most of the involved individuals had been vaccinated. While this year's incidence far exceeds the frequency typical of the last decade, it is still considered to be "well within the five percent failure rate common in vaccines, and is typical of measle transmission."

Parents are allowed to choose which vaccines their children will be exempt from taking. In practice, parents generally object to all vaccines if they object to any.

WISCONSIN

Craig Leutzinger, Immunization Program Director, Wisconsin Department of Public Health, indicated that Wisconsin's mandatory immunization law included medical and religious exemptions when it was instituted in 1975. It was ineffective in that it covered only kindergartners, and the wording did not require parents to have children vaccinated. Amendments in 1980 expanded coverage to grades K - 12 (to be implemented gradually), changed the wording to require vaccinations, and added the personal exemption. In spite of Department of Health opposition, the exemption was included through lobbying efforts of a group known as Dissatisfied Parents Together (DPT), which was led by a woman whose son had been severely injured by the DPT vaccine.

Immunization is a widely accepted practice in Wisconsin as reflected by a 99 percent compliance rate. Since 1977, the total percentage of exemptions has remained constant at 0.8 percent to one percent. Prior to 1980, the one percent reflected equal numbers of religious and medical exemptions; since 1980, religious and medical exemptions have dropped to 0.1 percent each while personal exemptions have remained steady at 0.6 percent. It appears that individuals who might previously have claimed religious exemptions now call their objections philosophical rather than religious.

In spite of the high compliance rate, Wisconsin had the highest state rate of mumps in 1987. The incidence of measles in Wisconsin was also high (284 in Wisconsin compared to 12 in Colorado). This does not necessarily correlate to the personal exemption, however, because Wisconsin's mandatory immunization law was set up to be implemented in stages. For example, vaccination for mumps was required beginning in 1982, and only grades K - 4 are currently covered; if an unvaccinated fifth-grader from another state enters a Wisconsin school, there is no requirement that the child be vaccinated against mumps. Another important factor in the high incidence of disease in Wisconsin is that until 1987 there was a strong reluctance on the part of schools to exclude unvaccinated individuals from school during disease outbreaks, even though the law allowed for it. In 1987, during an outbreak of measles, the need to protect unvaccinated children and to interrupt the transmission cycle overcame that reluctance. Since then, exclusion from school has become widely accepted. Outbreaks have "certainly included uncovered children," but no statistics are available on the percentages.

As in Colorado, parents have the right to select which vaccinations their children will be exempt from taking; however, generally there is an all or nothing attitude.

UTAH

According to Rick Crankshaw, Immunization Program Coordinator, Utah Department of Health, Utah's mandatory immunization law included only entering kindergartners when it was enacted in 1976. An amendment in 1982 expanded the coverage to grades K - 12, included all licenced child care facilities, and incorporated the personal exemption. The inclusion of the personal exemption was based on other states' experience with the DPT controversy over vaccinations for pertussis--which sometimes causes extremely serious adverse reactions.

The compliance rate in Utah is very high; exemptions during the last several years have been approximately one percent. Of that, 0.8 percent are personal exemptions and the other 0.2 percent are medical exemptions. No statistics directly comparing compliance rates before and after incorporation of the personal exemption are available.

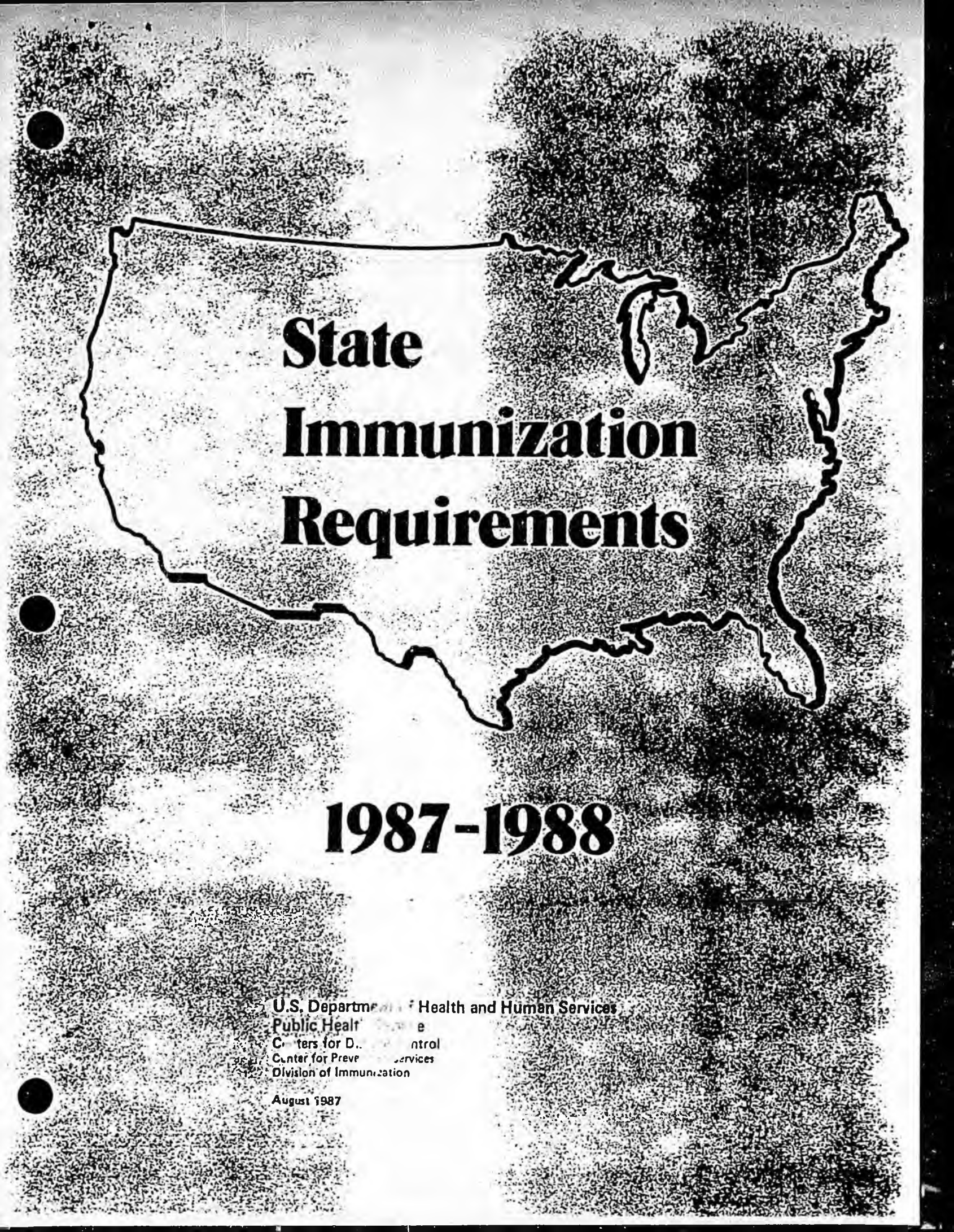
No statistics are available on the frequency of disease before and after incorporation of the personal exemption. Because of the law, Utah schools now have an accurate tracking system so that each school can make an immunization assessment. During an outbreak of disease, the Department of Health orders that any unprotected children be excluded from school until the outbreak is over.

As in Colorado and Wisconsin, parents can choose individual vaccinations to which they are philosophically opposed. In practice, however, parents generally object to all vaccinations or to none.

According to the results of this sample, and the Center for Disease Control, the availability of the personal exemption appears to have had relatively little significance. Feared problems have not materialized; the philosophical exemption does, however, weaken the force of immunization laws inasmuch as it provides some potential for sustaining transmission of disease.

I have requested a copy of the Center for Disease Control's most recent update of State Immunization Requirements, which I will forward to you.

I hope you find this information useful. Please contact me if you have any questions.



State Immunization Requirements

1987-1988

U.S. Department of Health and Human Services
Public Health Service
Centers for Disease Control
Center for Prevention Services
Division of Immunization

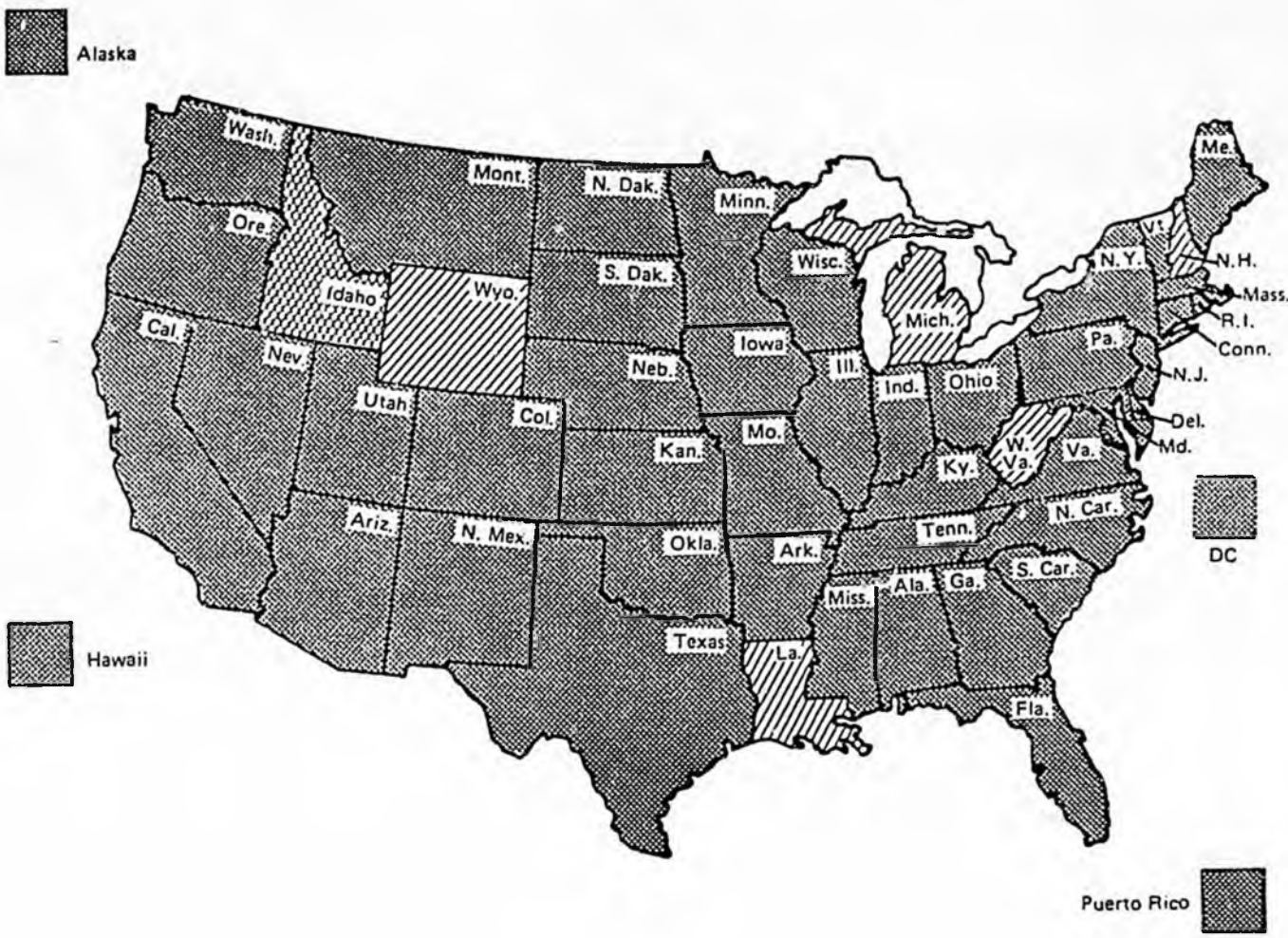
August 1987

CONTENTS

State Immunization Requirements
Applicable to Any or All of Grades K-12

State	Diphtheria	Tetanus	Pertussis	Measles	Mumps	Rubella	Polio
Alabama	K-12	K-12	K-6 yrs	K-12	K-12	K-12	K-12
Alaska	K-12	K-12	K-6 yrs	K-12	Not Required	K-11 yrs	K-12
Arizona	K-12	Not Required	Not Required	K-12	Not Required	K-12	K-12
Arkansas	K-12	K-12	K-6 yrs	K-12	Not Required	K-12	K-12
California	K-12	K-12	K-6 yrs	K-12	K-6 yrs	K-12	K-12
Colorado	K-12	K-12	K-6 yrs	K-12	K	K-6	K-12
Connecticut	K-12	K-12	K-6 yrs	K-12	K-12	K-12	K-12
Delaware	K-12	K-12	K-6 yrs	K-12	K-8	K-12	K-12
Dist. of Col.	K-12	K-12	K-6 yrs	K-12	K-12	K-12	K-12
Florida	K-12	K-12	K-6 yrs	K-12	K-12	K-12	K-12
Georgia	K-12	K-12	K-6 yrs	K-12	K-12	K-12	K-12
Hawaii	K-12	K-12	K-6 yrs	K-12	K-12	K-12	K-12
Idaho	K-5	K-5	Not Required	K-5	K-5	K-5	K-5
Illinois	K-12	K-12	K-5 yrs	K-12	K-12	K-12	K-12
Indiana	K-12	K-12	K-6 yrs	K-12	K-1	K-12	K-12
Iowa	K-12	K-12	K-6 yrs	K-12	Not Required	K-12	K-12
Kansas	K-12	K-12	K-6 yrs	K-12	K-12	K-12	K-12
Kentucky	K-12	K-12	Not Required	K-12	Not Required	K-12	K-12
Louisiana	New Enterers	New Enterers	New Enterers	New Enterers	New Enterers	New Enterers	New Enterers
Maine	K-12	K-12	K-6 yrs	K-12	K-8	K-12	K-12
Maryland	K-12	K-12	K-6 yrs	K-12	Not Required	K-12	K-12
Massachusetts	K-12	K-12	K-6 yrs	K-12	K-12	K-12	K-12
Michigan	New Enterers	New Enterers	New Enterers	New Enterers	New Enterers	New Enterers	New Enterers
Minnesota	K-12	K-12	K-6 yrs	K-12	K-6 yrs	K-12	K-12
Mississippi	K-12	K-12	K-6 yrs	K-12	Not Required	K-12	K-12
Missouri	K-12	Not Required	Not Required	K-12	Not Required	K-12	K-12
Montana	K-12	K-12	Not Required	K-12	Not Required	K-12	K-12
Nebraska	K-12	K-12	K-6 yrs	K-12	K-12	K-12	K-12
Nevada	K-12	K-12	K-6 yrs	K-12	Not Required	K-12	K-12
New Hampshire	New Enterers	New Enterers	New Enterers	New Enterers	New Enterers	New Enterers	New Enterers
New Jersey	K-12	K-12	K-6 yrs	K-12	K-14 yrs	K-12	K-12
New Mexico	K-12	K-12	K-6 yrs	K-12	Not Required	K-12	K-12
New York	K-12	Not Required	Not Required	K-12	K-12	K-12	K-12
North Carolina	K-12	K-12	K-6 yrs	K-12	K-12	K-12	K-12
North Dakota	K-12	K-12	K-6 yrs	K-12	K-12	K-12	K-12
Ohio	K-12	K-12	K-6 yrs	K-12	K-12	K-12	K-12
Oklahoma	K-12	K-12	K-6 yrs	K-12	Not Required	K-12	K-12
Oregon	K-12	K-12	Not Required	K-12	New Enterers	K-12	K-12
Pennsylvania	K-12	K-12	Not Required	K-12	K-12	K-12	K-12
Puerto Rico	K-12	K-12	K-6 yrs	K-12	K-12	K-12	K-12
Rhode Island	K-12	K-12	Not Required	K-12	K-6 yrs	K-12	K-12
South Carolina	K-12	K-12	K-5 yrs	K-12	Not Required	K-12	K-12
South Dakota	K-12	K-12	K-6 yrs	K-12	K-12	K-12	K-12
Tennessee	K-12	K-12	K-6 yrs	K-12	Not Required	K-12	K-12
Texas	K-12	K-12	Not Required	K-12	K-15 yrs	K-11 yrs	K-12
Utah	K-12	K-12	K-6 yrs	K-12	K-12	K-12	K-12
Vermont	K-12	K-12	K-6 yrs	K-12	Not Required	K-12	K-12
Virginia	K-12	K-12	K-6 yrs	K-12	New Enterers	K-12	K-12
Washington	K-12	K-12	Not Required	K-12	K1	K-12	K-12
West Virginia	New Enterers	New Enterers	New Enterers	New Enterers	Not Required	New Enterers	New Enterers
Wisconsin	K-12	K-12	K-6 yrs	K-12	K-4	K-11 yrs	K-12
Wyoming	New Enterers	New Enterers	K-6 yrs	New Enterers	New Enterers	New Enterers	New Enterers

DIPHTHERIA
Immunization Requirements
(For Any or All of Grades K-12)



New Enterers

K-5th Grade

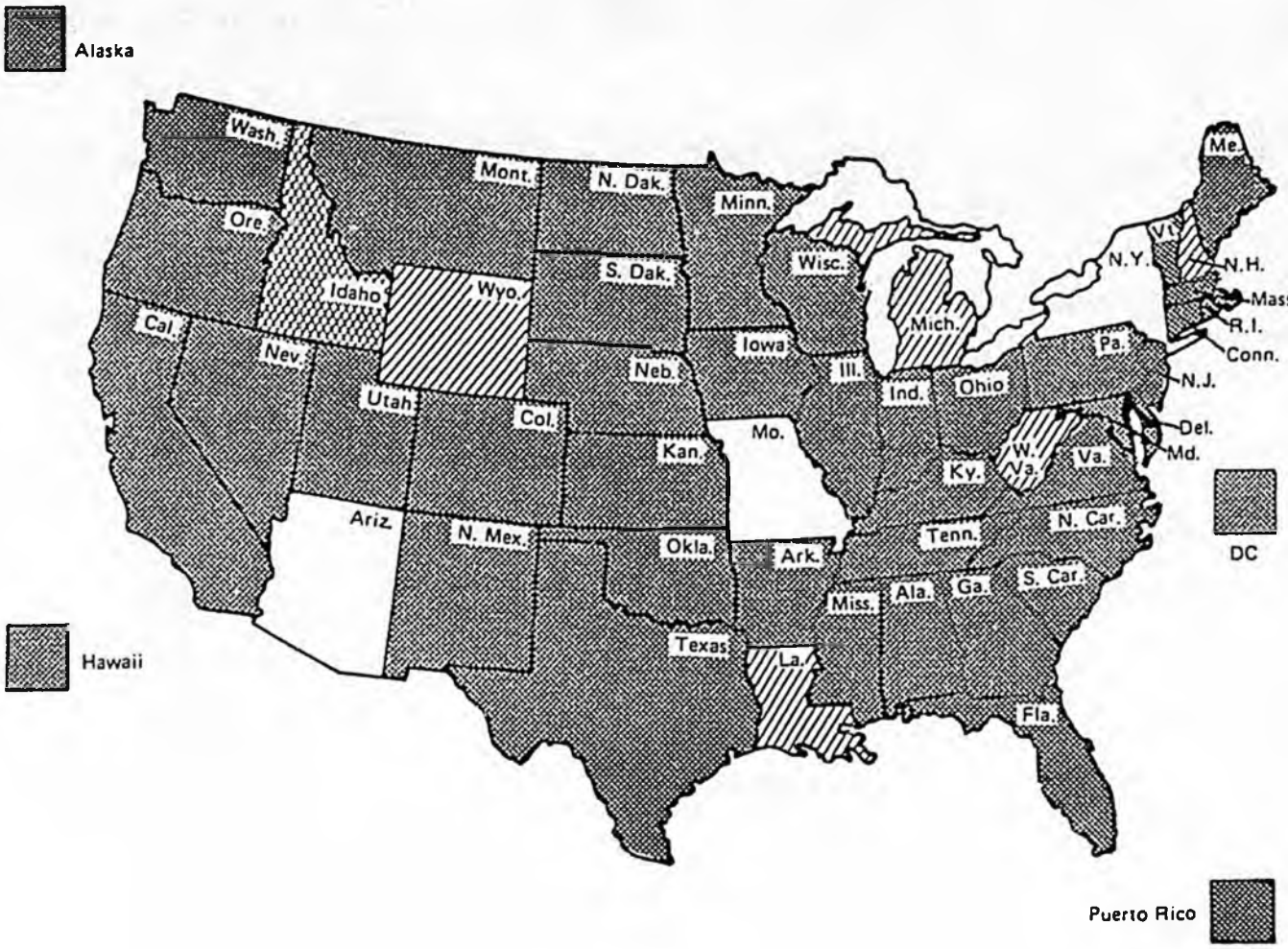
K-12th Grade

DIPHTHERIA

State Immunization Requirements
Applicable to Any or All of Grades K-12

State	Grade	Dosage Requirements and Additional Comments
Alabama	K-12	3 dose minimum required
Alaska	K-12	5 doses unless 4th dose after 4th birthday, then 4; 3 doses if 7 years and older
Arizona	K-12	5 doses unless 4th dose after 4th birthday
Arkansas	K-12	3 doses; last must have been after 4th birthday
California	K-12	4 doses; 4th dose after 2nd birthday
Colorado	K-12	4 doses
Connecticut	K-12	3 doses
Delaware	K-12	3 doses
Dist. of Col.	K-12	3 doses plus booster if series started as infant; a 5th dose is recommended; also required of college students
Florida	K-12	5 doses unless 4th dose after 4th birthday, then 4; 3 doses if 7 yrs & older
Georgia	K-12	3 doses minimum; the last dose given after 4th birthday
Hawaii	K-12	As recommended by American Academy of Pediatrics
Idaho	K-5	4 doses
Illinois	K-12	4 doses; the last a booster on or after 4th birthday plus a 10 year booster
Indiana	K-12	4 doses for K-1, 3 doses for grades 2 and above
Iowa	K-12	3 doses, one must be after age 4 years
Kansas	K-12	4 doses if series is begun before age 7 years; 3 if begun after 6 years
Kentucky	K-12	3 to 5 doses—the last a booster on or after 4th birthday plus a 10 year booster
Louisiana	New Enterers	4 to 5 doses; at least 1 dose after age 4 years
Maine	K-12	3 doses
Maryland	K-12	4 doses minimum, with 1 after 4 years of age
Massachusetts	K-12	4 doses for K; 3 doses plus 10 year booster for 1-12
Michigan	New Enterers	4 doses, only 3 if series started after 6 years, plus booster every 10 years
Minnesota	K-12	4 doses
Mississippi	K-12	4 doses if before 7 years; 3 if after 7 years; at least 1 booster dose after 4 years
Missouri	K-12	3 doses, at least 1 after age 3 years
Montana	K-12	4 doses if 6 years old or less; 3 if 7 years or older; last dose after 4th birthday
Nebraska	K-12	3 doses
Nevada	K-12	4 to 5 dose.
New Hampshire	New Enterers	5 doses; 4 if 4th is on or after 4th birthday; 3 if over 6 years and 3rd dose given on or after 4th birthday
New Jersey	K-12	4 doses including booster for ages 1-6; 3 doses for 7 years and older
New Mexico	K-12	4 doses if begun before age 7 years; 3 if after age 7 years; at least 1 dose after 4th birthday
New York	K-12	3 doses
North Carolina	K-12	5 doses; 3 doses by 1 yr of age, 1 booster dose in 2nd yr, 1 booster dose on or after 4th birthday
North Dakota	K-12	4 doses
Ohio	K-12	4 doses; 3 if 3rd on or after 6th birthday
Oklahoma	K-12	3 doses
Oregon	K-12	4 doses; 5 if 4th was before age 4 years; 3 for grades 2-12 if in Oregon Schools on 3 14 82 unless 1 or more before 6 months, then 4 doses
Pennsylvania	K-12	3 doses
Puerto Rico	K-12	3 - doses, provided the 3rd is given after 4th birthday
Rhode Island	K-12	3 doses
South Carolina	K-12	3 doses, at least 1 must have been on or after 4th birthday
South Dakota	K-12	4 doses, at least 1 must have been after 4th birthday
Tennessee	K-12	4 doses
Texas	K-12	3 doses, 1 dose after 4th birthday plus 1 within 10 years
Utan	K-12	4 doses
Vermont	K-12	3 doses, with 6 months between 2nd dose and any thereafter
Virginia	K-12	3 doses, with 3rd after 4th birthday
Washington	K-12	3 doses, last dose must be at or after age 4 years
West Virginia	New Enterers	3 doses minimum, with at least 1 after 4th birthday
Wisconsin	K-12	4 doses, only 3 if 3rd received after 4th birthday

TETANUS
Immunization Requirements
(For Any or All of Grades K-12)



Not Required

New Enterers

K-5th Grade

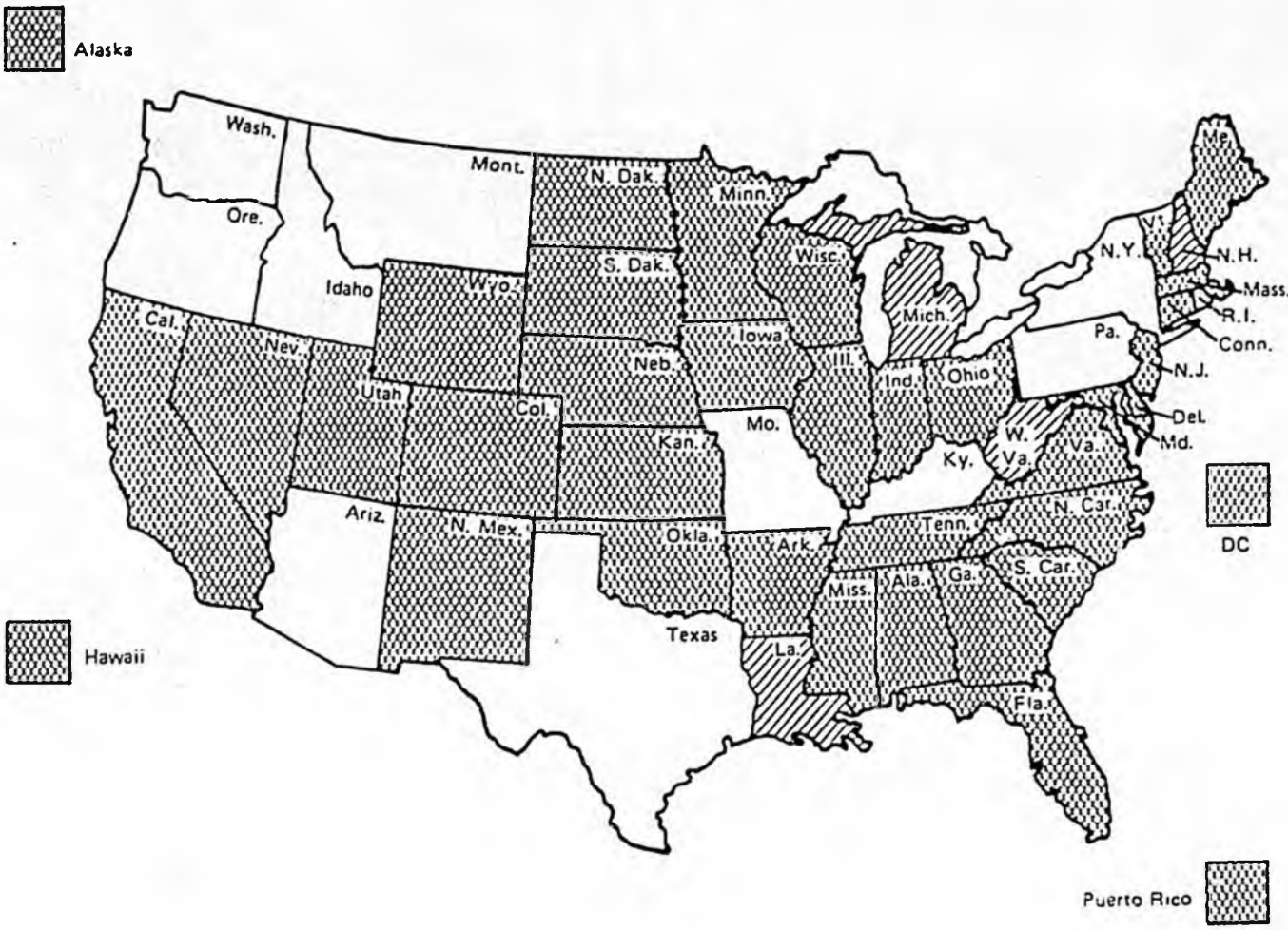
K-12th Grade

TETANUS

State Immunization Requirements
Applicable to Any or All of Grades K-12

State	Grade	Dosage Requirements and Additional Comments
Alabama	K-12	3 dose minimum required
Alaska	K-12	5 doses unless 4th dose after 4th birthday, then 4 doses; 3 doses if 7 years and older
Arizona	Not Required	Usually given with diphtheria
Arkansas	K-12	3 doses, but last must have been since 4th birthday
California	K-12	4 doses, 4th dose after 2nd birthday
Colorado	K-12	4 doses
Connecticut	K-12	3 doses
Delaware	K-12	3 doses
Dist. of Col.	K-12	3 doses plus booster if series started as infant; a 5th dose is recommended; also required of college students
Florida	K-12	5 doses unless 4th dose after 4th birthday, then 4; 3 doses if 7 yrs & older
Georgia	K-12	3 doses minimum; the last dose given after the 4th birthday
Hawaii	K-12	As recommended by American Academy of Pediatrics
Idaho	K-5	4 doses
Illinois	K-12	4 doses; the last a booster on or after 4th birthday plus a 10 year booster
Indiana	K-12	4 doses for K-1, 3 doses for grades 2 and above
Iowa	K-12	3 doses, 1 must be after age 4 years
Kansas	K-12	4 doses if started before age 7 years; 3 if begun after 7 years
Kentucky	K-12	3 to 5 doses—the last a booster on or after 4th birthday plus a 10 year booster
Louisiana	New Enterers	4 to 5 doses; at least 1 dose after age 4 years
Maine	K-12	3 doses
Maryland	K-12	4 doses minimum, with 1 after 4 years of age
Massachusetts	K-12	4 doses for K; 3 doses plus 10 year booster for 1-12
Michigan	New Enterers	4 doses, only 3 if series started after 6 years of age, plus booster every 10 years
Minnesota	K-12	4 doses
Mississippi	K-12	4 doses if before 7 years; 3 if after 7 years; at least 1 booster dose after 4 years
Missouri	Not Required	3 doses, at least 1 after age 3 years recommended
Montana	K-12	4 doses if 6 years or less; 3 if 7 years or older; last dose after 4th birthday
Nebraska	K-12	3 doses
Nevada	K-12	4 to 5 doses
New Hampshire	New Enterers	5 doses; 4 if 4th is on or after 4th birthday, 3 if over 6 years and 3rd given on or after 4th birthday
New Jersey	K-12	4 doses including booster for ages 1-6; 3 doses for 7 years and older
New Mexico	K-12	4 doses if begun before age 7 years; 3 if begun at age 7 years or older; at least 1 dose after 4th birthday
New York	Not Required	
North Carolina	K-12	5 doses; 3 doses by 1 yr of age, 1 booster dose in 2nd yr, 1 booster dose on or after 4th birthday
North Dakota	K-12	4 doses
Ohio	K-12	4 doses; 3 if 3rd received on or after 6th birthday
Oklahoma	K-12	3 doses
Oregon	K-12	4 doses; 5 if 4th was before age 4 years; 3 for grades 2-12 if in Oregon Schools on 3 14 82 unless 1 or more before 6 months, then 4 doses
Pennsylvania	K-12	3 doses
Puerto Rico	K-12	3 + doses, provided the 3rd is given after 4th birthday
Rhode Island	K-12	3 doses
South Carolina	K-12	3 doses, at least 1 must have been on or after 4th birthday
South Dakota	K-12	4 doses, at least 1 must have been after 4th birthday
Tennessee	K-12	4 doses
Texas	K-12	3 doses, 1 dose after 4th birthday plus 1 within 10 years
Utah	K-12	4 doses
Vermont	K-12	3 doses, with 6 months between 2nd dose and any thereafter; plus booster in 10 years
Virginia	K-12	3 doses, with 3rd after 4th birthday
Washington	K-12	3 doses, last dose must be at or after age 4 years
West Virginia	New Enterers	3 doses minimum, with at least 1 after 4th birthday
Wisconsin	K-12	4 doses, only 3 doses if 3rd received after 4th birthday

PERTUSSIS
Immunization Requirements
(For Any or All of Grades K-12)



Not Required

New Enterers

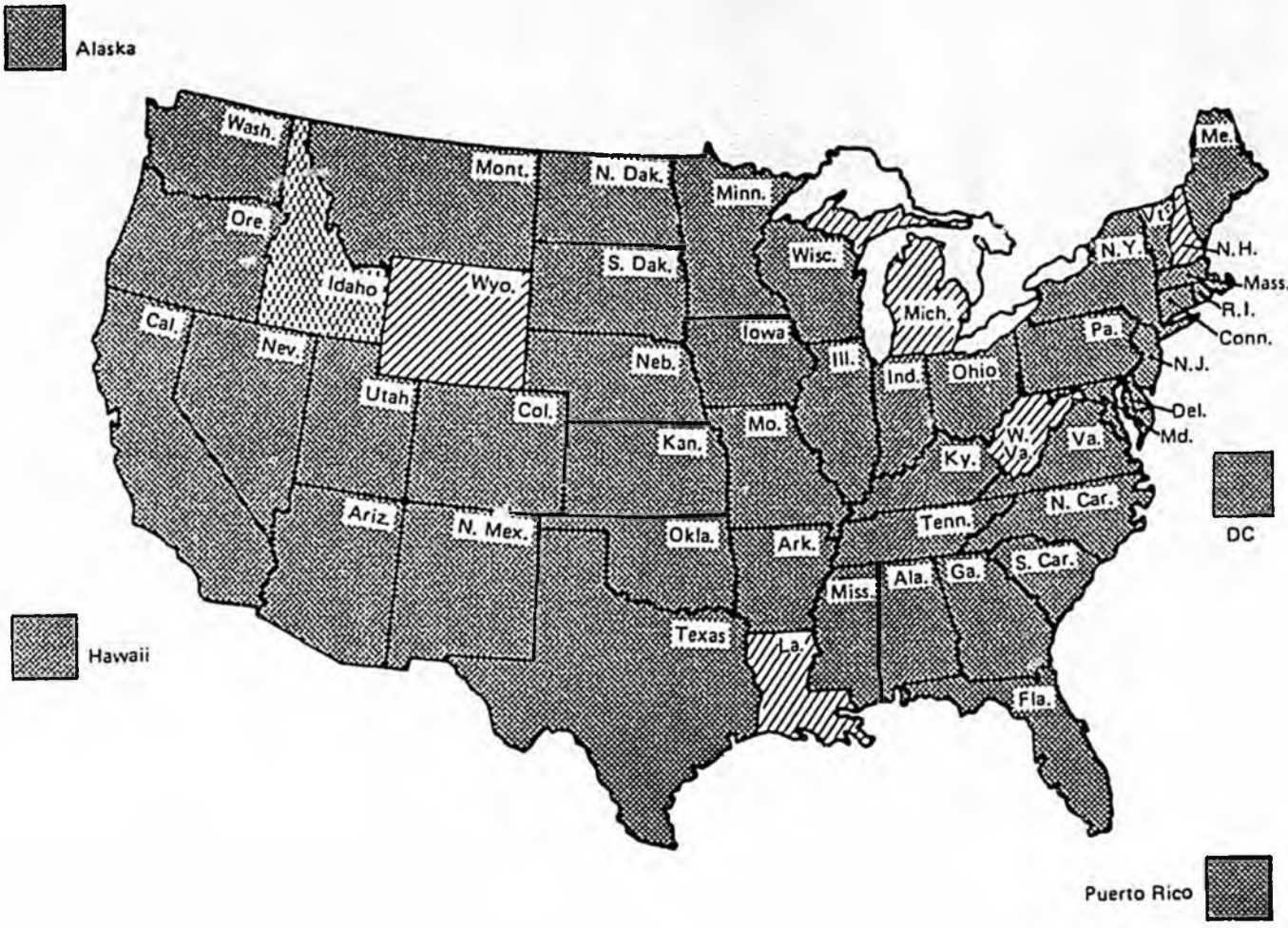
K-5 yrs or K-6 yrs

PERTUSSIS

State Immunization Requirements
Applicable to Any or All of Grades K-12

State	Grade	Dosage Requirements and Additional Comments
Alabama	K-6 yrs	3 dose minimum required
Alaska	K-6 yrs	5 doses unless 4th dose after 4th birthday, then 4 doses
Arizona	Not Required	Usually given with diphtheria
Arkansas	K-6 yrs	3 doses, but last must have been after 4th birthday
California	K-6 yrs	4 doses, 4th dose after 2nd birthday
Colorado	K-6 yrs	4 doses
Connecticut	K-6 yrs	3 doses
Delaware	K-6 yrs	3 doses
Dist. of Col.	K-6 yrs	3 doses
Florida	K-6 yrs	5 doses unless 4th dose after 4th birthday; then 4 doses
Georgia	K-6 yrs	3 doses minimum; the last dose given after the 4th birthday
Hawaii	K-6 yrs.	As recommended by American Academy of Pediatrics
Idaho	Not Required	
Illinois	K-5 yrs	4 doses; the last a booster on or after 4th birthday
Indiana	K-6 yrs	4 doses
Iowa	K-6 yrs	3 doses, 1 must be after age 4 years
Kansas	K-6 yrs	4 doses
Kentucky	Not Required	
Louisiana	New Enterers	4 to 5 doses; at least 1 after age 4 years; required to age 7 years
Maine	K-6 yrs	3 doses
Maryland	K-6 yrs	Minimum 4 doses with 1 after 4 years of age
Massachusetts	K-6 yrs	4 doses
Michigan	New Enterers	4 doses, not required after 6th birthday
Minnesota	K-6 yrs	4 doses
Mississippi	K-6 yrs	4 doses if before 7 years; at least 1 booster after 4th birthday
Missouri	Not Required	3 doses, at least 1 after age 3 years recommended
Montana	Not Required	Usually given with diphtheria-tetanus
Nebraska	K-6 yrs	3 doses
Nevada	K-6 yrs	4 to 5 years
New Hampshire	New Enterers	5 doses; 4 if 4th given on or after 4th birthday; not required to be given if 7 years or older
New Jersey	K-6 yrs	4 doses
New Mexico	K-6 yrs	4 doses
New York	Not Required	
North Carolina	K-6 yrs	5 doses; 3 doses by 1 yr of age, 1 booster dose in 2nd yr, 1 booster dose on or after 4th birthday
North Dakota	K-6 yrs	4 doses
Ohio	K-6 yrs	4 doses; 3 if 3rd dose required on or after 6th birthday
Oklahoma	K-6 yrs	3 doses
Oregon	Not Required	
Pennsylvania	Not Required	
Puerto Rico	K-6 yrs	3 doses, if 3rd is given after 4th birthday; not required after 7th birthday
Rhode Island	Not Required	
South Carolina	K-5 yrs	3 doses, at least 1 received on or after 4th birthday
South Dakota	K-6 yrs	4 doses, at least 1 received after 4th birthday
Tennessee	K-6 yrs	4 doses
Texas	Not Required	
Utah	K-6 yrs	4 doses
Vermont	K-6 yrs	3 doses, 6 months between 2nd and any thereafter
Virginia	K-6 yrs	3 doses, with 3rd dose after 4th birthday
Washington	Not Required	
West Virginia	New Enterers	3 doses minimum, with at least 1 after 4th birthday; not required after 6 years of age
Wisconsin	K-6 yrs	4 doses, only 3 doses if 3rd received after 4th birthday
Wyoming	K-6 yrs	4 doses; required up to but not including 7th birthday

MEASLES
Immunization Requirements
(For Any or All of Grades K-12)



New Enterers

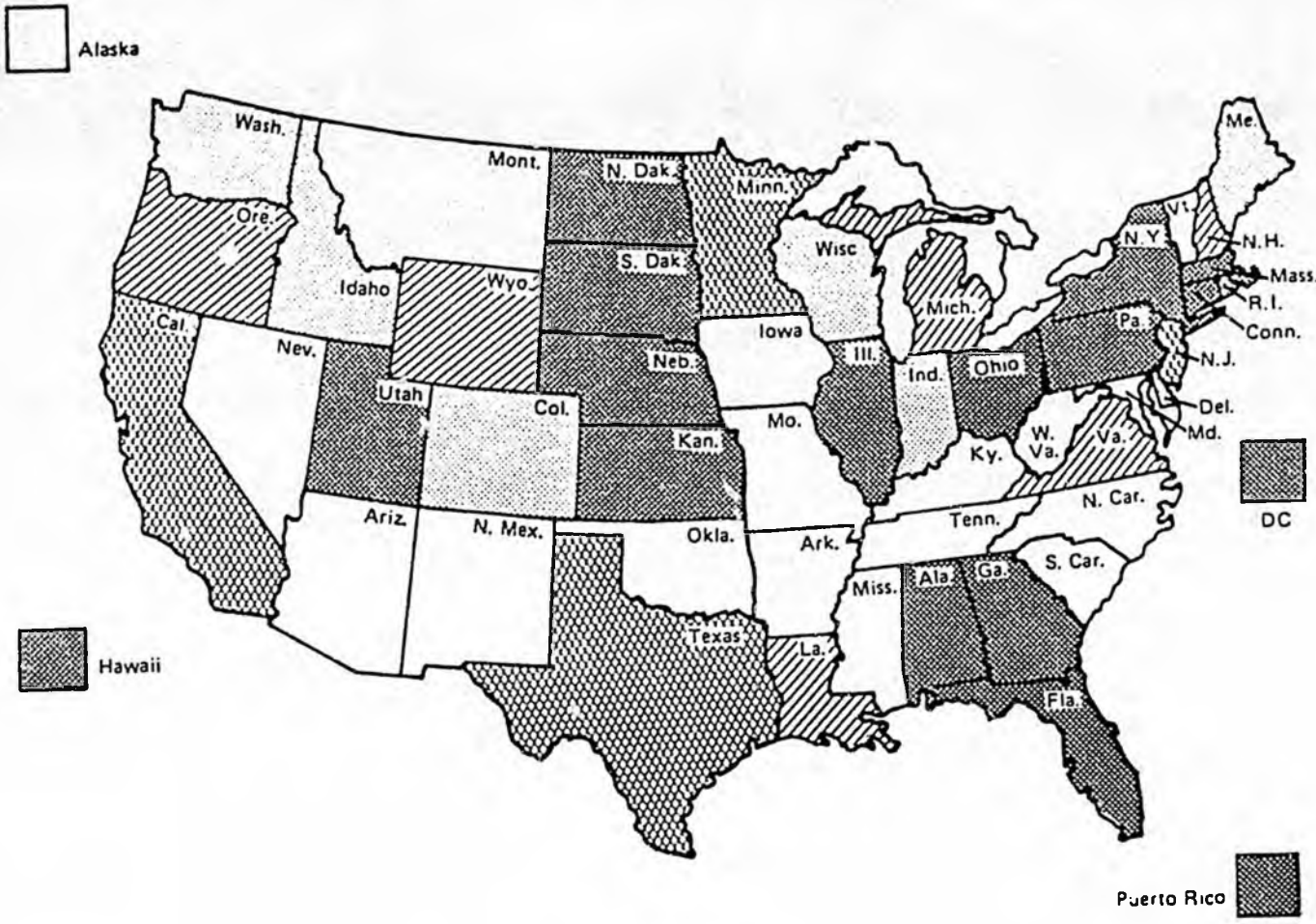
K-5th Grade

K-12th Grade

State Immunization Requirements Applicable to Any or All of Grades K-12

State	Grade	Dosage Requirements and Additional Comments
Alabama	K-12	1 dose after 15 months of age
Alaska	K-12	1 dose on or after 1st birthday
Arizona	K-12	1 dose live measles vaccine given on or after 1st birthday
Arkansas	K-12	1 dose given after 1st birthday and after January 1968
California	K-12	1 dose of live virus vaccine administered on or after 1st birthday
Colorado	K-12	1 dose on or after 1st birthday
Connecticut	K-12	1 dose after age 1 and vaccine did not include gamma globulin
Delaware	K-12	1 dose after 1 year of age
Dist. of Col.	K-12	1 dose, must be repeated if given before 1969; also required of college students
Florida	K-12	1 dose at 15 months recommended, over 12 months accepted; and in 1968 or later
Georgia	K-12	1 dose of live virus vaccine given after the 1st birthday and after 1968; or positive serology
Hawaii	K-12	1 dose as recommended by American Academy of Pediatrics
Idaho	K-5	1 dose after 1st birthday; MD diagnosis of disease or laboratory confirmation of immunity accepted
Illinois	K-12	1 dose at 15 months of age or later; MD diagnosis of disease or laboratory confirmation accepted
Indiana	K-12	1 dose at or after 12 months of age
Iowa	K-12	1 dose after 15 months of age or physician's diagnosis
Kansas	K-12	1 dose given after 12 months of age
Kentucky	K-12	1 dose on or after 12 months of age, recommended 15 months
Louisiana	New Enterers	1 dose given on or after 15 months, 12 to 15 months also accepted
Maine	K-12	1 dose at 12 months of age or older or serologic confirmation of immunity
Maryland	K-12	1 dose live vaccine at 1 year or older or titer of 1:4 or greater
Massachusetts	K-12	1 dose at or after 12 months of age
Michigan	New Enterers	1 dose after 1st birthday; MD diagnosis of disease accepted
Minnesota	K-12	1 dose after 11 months 15 days of age
Mississippi	K-12	1 dose after 1st birthday
Missouri	K-12	1 dose given after 12 months of age; children born in or after 1982 at 15 months
Montana	K-12	1 dose given after 12 months of age
Nebraska	K-12	1 dose at or after 12 months of age
Nevada	K-12	1 dose after 12 months of age
New Hampshire	New Enterers	1 dose live vaccine on or after 1st birthday
New Jersey	K-12	1 dose live virus vaccine given after 12 months of age
New Mexico	K-12	1 dose live virus given on or after 12 months of age
New York	K-12	1 dose live vaccine administered after 12 months of age, but recommended at 15 months
North Carolina	K-12	1 dose live vaccine on or after 1st birthday
North Dakota	K-12	1 dose if given after 15 months of age; 12 months accepted
Ohio	K-12	1 dose live virus vaccine on or after 1st birthday
Oklahoma	K-12	1 dose, received on or after 1st birthday
Oregon	K-12	1 dose at or after 12 months of age, but recommended at 15 months
Pennsylvania	K-12	1 dose live vaccine on or after 1st birthday, or positive serology
Puerto Rico	K-12	1 dose live virus vaccine recommended to be given at or after 15 months of age
Rhode Island	K-12	1 dose after 12 months of age; also required of college students
South Carolina	K-12	1 dose, must have been on or after 1st birthday
South Dakota	K-12	1 dose after 12 months of age or MD's diagnosis of disease; also required by State funded colleges
Tennessee	K-12	1 dose given after 12 months of age
Texas	K-12	1 dose on, after, or during the calendar month of the 1st birthday or physician verified history of disease
Utah	K-12	1 dose given after 12 months of age
Vermont	K-12	1 dose administered on or after 1st birthday or a MD diagnosed disease history
Virginia	K-12	1 dose after 12 months of age
Washington	K-12	1 dose of live vaccine after 1st birthday
West Virginia	New Enterers	1 dose given after 12 months of age
Wisconsin	K-12	1 dose on or after 1st birthday

MUMPS
Immunization Requirements
(For Any or All of Grades K-12)



Not Required

New Enterers

K, K-1st, K-4th, K-5th, or K-8th Grade

K-6yrs, K-14yrs, or K-15yrs

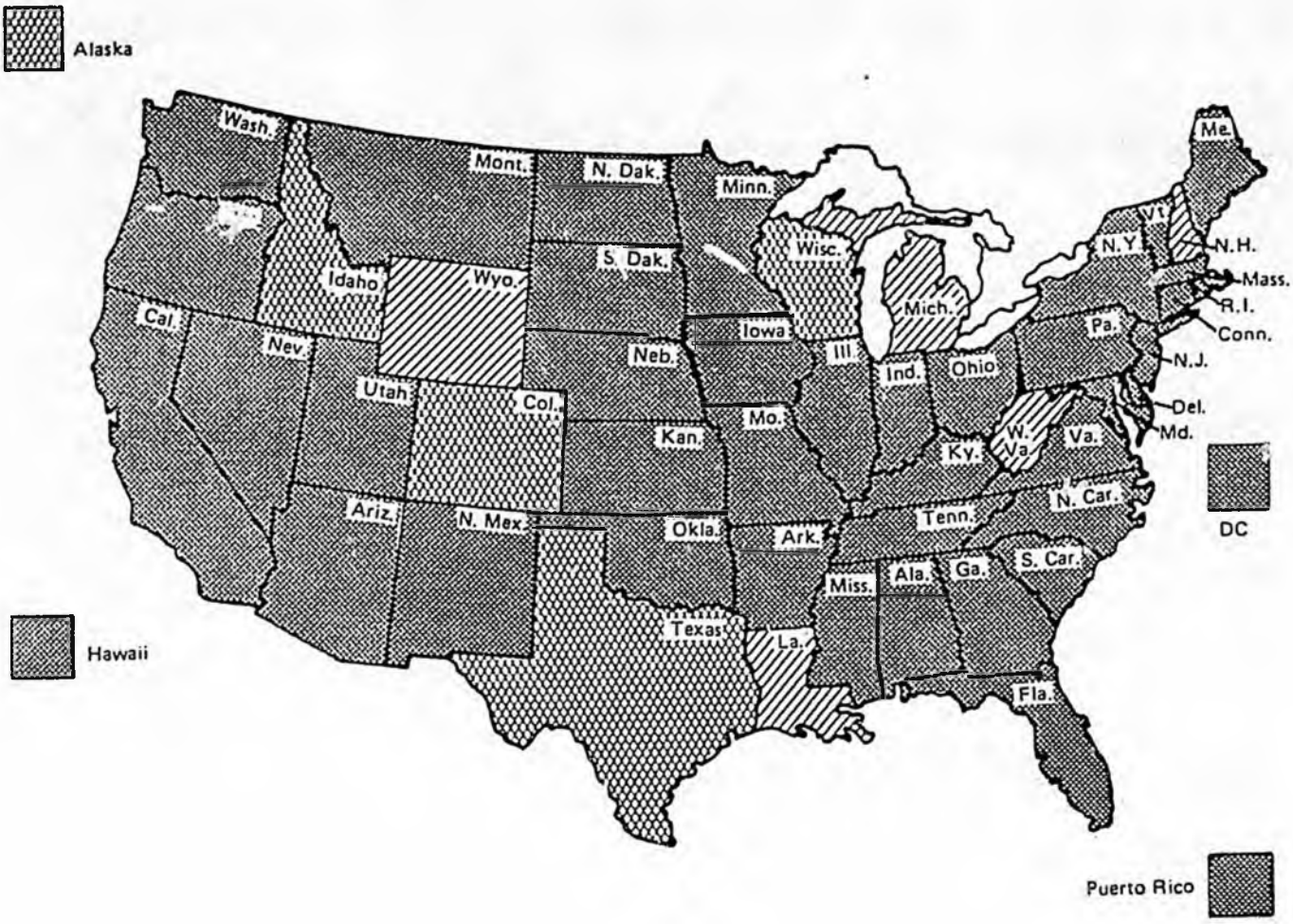
K-12th Grade

MUMPS

State Immunization Requirements
Applicable to Any or All of Grades K-12

State	Grade	Dosage Requirements and Additional Comments
Alabama	K-12	1 dose after 15 months of age
Alaska	Not Required	
Arizona	Not Required	Usually given with measles and rubella vaccine
Arkansas	Not Required	
California	K-6 yrs	1 dose administered on or after 1st birthday
Colorado	K	1 dose on or after 1st birthday, not required after K
Connecticut	K-12	1 dose given after age 1 year
Delaware	K-8	1 dose after 1 year of age; K-9 in 88-89, K-10 in 89-90 etc.
Dist. of Col.	K-12	1 dose, also required of college students
Florida	K-12	1 dose at 15 months recommended, over 12 months accepted
Georgia	K-12	1 dose of live virus vaccine given after the 1st birthday
Hawaii	K-12	1 dose as recommended by American Academy of Pediatrics
Idaho	K-5	1 dose after 1st birthday; MD diagnosis of disease or laboratory confirmation of immunity accepted
Illinois	K-12	1 dose at 1 year of age or later, or MD diagnosis of disease
Indiana	K-1	1 dose at or after 12 months of age; 1 additional grade each year
Iowa	Not Required	
Kansas	K-12	1 dose given after 12 months of age
Kentucky	Not Required	
Louisiana	New Enterers	1 dose given on or after 15 months; 12 to 15 months also accepted
Maine	K-8	1 dose at 12 months of age or older or serologic confirmation of immunity
Maryland	Not Required	
Massachusetts	K-12	1 dose at or after 12 months of age
Michigan	New Enterers	1 dose, only in K-4 and entered K in 1979 or later
Minnesota	K-6 yrs	1 dose
Mississippi	Not Required	
Missouri	Not Required	1 dose, given on or after 15 months; recommended
Montana	Not Required	Highly recommended
Nebraska	K-12	1 dose at or after 12 months of age
Nevada	Not Required	
New Hampshire	New Enterers	1 dose
New Jersey	K-14 yrs	1 dose; required of those born on or after 1 1 73
New Mexico	Not Required	1 dose strongly recommended
New York	K-12	1 dose live vaccine given after 12 months of age
North Carolina	K-12	1 dose live vaccine by 2 yrs of age; not required for children who entered 1st grade before July 1, 1987
North Dakota	K-12	1 dose if given after 15 months of age — 12 months accepted
Ohio	K-12	1 dose live virus vaccine on or after 1st birthday
Oklahoma	Not Required	
Oregon	New Enterers	1 dose includes all out-of-state transferees but not students in grades 2-12 in Oregon schools on 3/14/82
Pennsylvania	K-12	1 dose on or after 1st birthday or MD diagnosis of disease
Puerto Rico	K-12	1 dose live virus vaccine recommended to be given at or after 15 months of age
Rhode Island	K-6 yrs	1 dose after 12 months of age
South Carolina	Not Required	
South Dakota	K-12	1 dose given after 12 months of age
Tennessee	Not Required	
Texas	K-15 yrs	1 dose or physician verified disease; an additional year of age to be added each year until K-12 coverage reached
Utah	K-12	1 dose given after 12 months of age
Vermont	Not Required	
Virginia	New Enterers	1 dose given at 12 months of age or older; required of all new enterers since 8 1 81
Washington	K-1	1 dose
West Virginia	Not Required	
Wisconsin	K-4	1 dose on or after 1st birthday; applied to one additional grade until K-12 coverage reached
		[illegible] entering Wyoming schools

RUBELLA
Immunization Requirements
(For Any or All of Grades K-12)



New Enterers

K-11 yrs, K-5th, or K-6th Grade

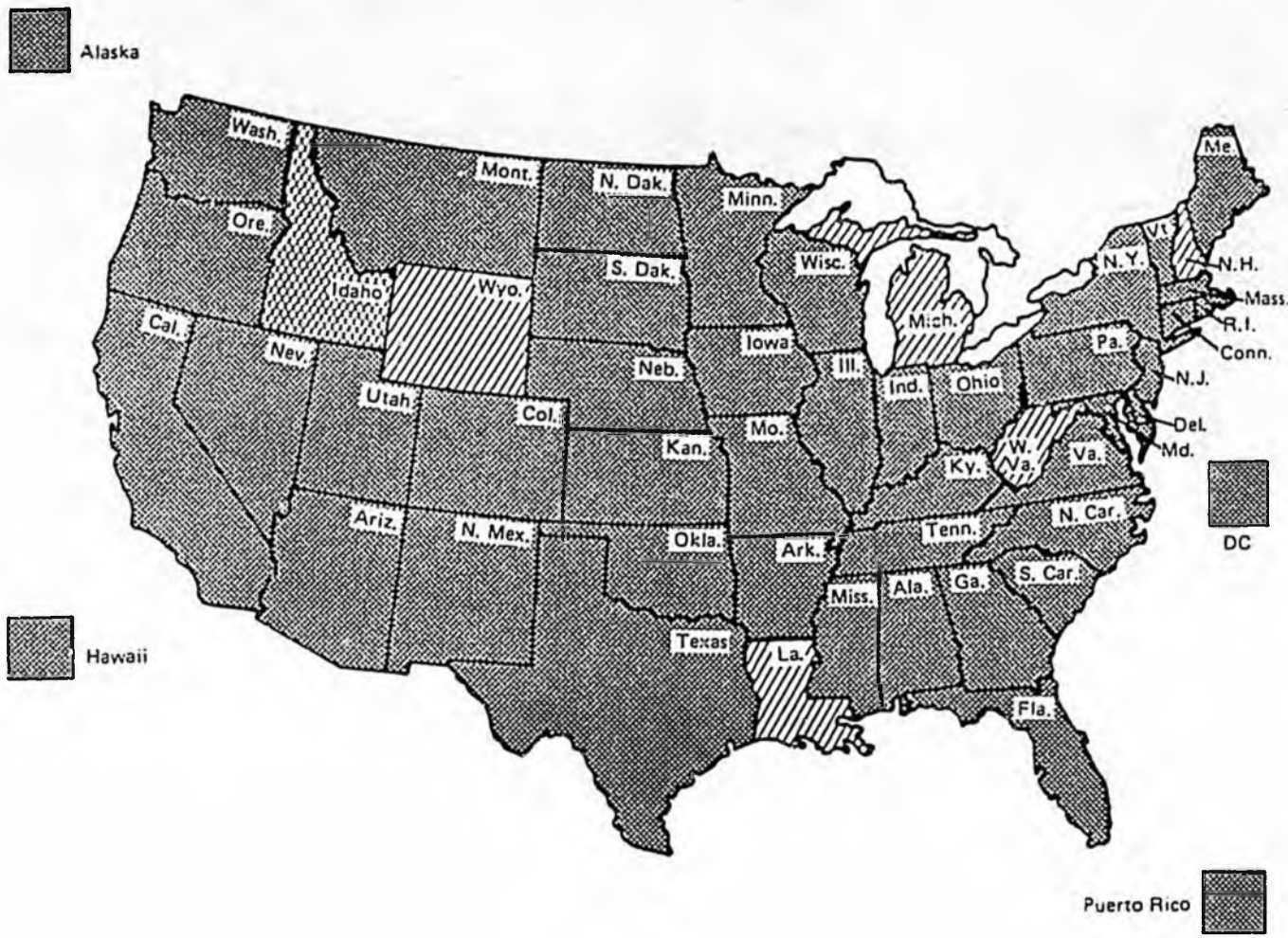
K-12th Grade

RUBELLA

State Immunization Requirements
Applicable to Any or All of Grades K-12

State	Grade	Dosage Requirements and Additional Comments
Alabama	K-12	1 dose administered after 15 months of age
Alaska	K-11 yrs	1 dose administered on or after 1st birthday
Arizona	K-12	1 dose given on or after 1st birthday
Arkansas	K-12	1 dose given after the 1st birthday and after 6/1/69
California	K-12	1 dose administered on or after 1st birthday
Colorado	K-6	1 dose on or after 1st birthday; post pubertal females exempt
Connecticut	K-12	1 dose given after 1 year of age
Delaware	K-12	1 dose given after 1 year of age
Dist. of Col.	K-12	1 dose; also required of college students
Florida	K-12	1 dose at 15 months of age recommended, over 12 months accepted
Georgia	K-12	1 dose of live virus vaccine given after the 1st birthday
Hawaii	K-12	1 dose, as recommended by American Academy of Pediatrics
Idaho	K-5	1 dose after 1st birthday; laboratory confirmation of immunity accepted
Illinois	K-12	1 dose at 1 year of age or later, or laboratory confirmation
Indiana	K-12	1 dose at or after 12 months of age
Iowa	K-12	1 dose after 15 months of age, or laboratory confirmation
Kansas	K-12	1 dose given after 12 months of age
Kentucky	K-12	1 dose on or after 12 months of age
Louisiana	New Enterers	1 dose given on or after 15 months of age; 12 to 15 months also accepted
Maine	K-12	1 dose at 12 months of age or older; or serologic confirmation of immunity
Maryland	K-12	1 dose of live vaccine or a titer of 1:8 or greater; in K-2, must have been administered on or after 1st birthday
Massachusetts	K-12	1 dose at or after 12 months of age
Michigan	New Enterers	1 dose given after the 1st birthday
Minnesota	K-12	1 dose; not required of females 12 years of age or older
Mississippi	K-12	1 dose after 12 months of age
Missouri	K-12	1 dose given after 12 months of age; children born in or after 1982, at 15 months
Montana	K-12	1 dose after 12 months of age; not required of females 12 years old or older
Nebraska	K-12	1 dose at or after 12 months of age
Nevada	K-12	1 dose after 12 months
New Hampshire	New Enterers	1 dose
New Jersey	K-12	1 dose
New Mexico	K-12	1 dose at 12 months of age
New York	K-12	1 dose live vaccine after 12 months of age; may be waived for females 11 years old and up
North Carolina	K-12	1 dose of live vaccine by age 2 years
North Dakota	K-12	1 dose, if given after 15 months of age — 12 months accepted
Ohio	K-12	1 dose live virus vaccine on or after 1st birthday
Oklahoma	K-12	1 dose; not required of females ages 12 years and above
Oregon	K-12	1 dose at or after 12 months of age, but recommended at 15 months
Pennsylvania	K-12	1 dose on or after 1st birthday, or positive serology
Puerto Rico	K-12	1 dose live virus vaccine recommended to be given at or after 15 months of age
Rhode Island	K-12	1 dose after 12 months of age; also required of college students
South Carolina	K-12	1 dose on or after 1st birthday; not required of females after onset of puberty
South Dakota	K-12	1 dose given after 12 months of age; or positive serology; also required by State funded colleges
Tennessee	K-12	1 dose on or after 12 months of age; females 13 years old and up are exempt
Texas	K-11 yrs	1 dose
Utah	K-12	1 dose given after 12 months of age
Vermont	K-12	1 dose given on or after 1st birthday, or positive serology
Virginia	K-12	1 dose given after 12 months of age or older
Washington	K-12	1 dose after 1 year; or positive serology
West Virginia	New Enterers	1 dose given after 12 months of age
Wisconsin	K-11 yrs	1 dose given on or after 1st birthday
Wyoming	New Enterers	1 dose after 12 months of age, entering Wyoming schools through age 10 years

POLIO
State Immunization Requirements
Applicable to Any or All of Grades K-12



New Enterers

K-5th Grade

K-12th Grade

POLIO
Immunization Requirements
(For Any or All of Grades K-12)

State	Grade	Dosage Requirements and Additional Comments
Alabama	K-12	3 dose minimum required
Alaska	K-12	4 doses unless 3rd dose after 4th birthday, then 3 doses
Arizona	K-12	5 doses unless 4th dose after 4th birthday, then 4 doses
Arkansas	K-12	3 doses, last must have been given after 4th birthday
California	K-12	3 doses, 3rd dose after 2nd birthday
Colorado	K-12	3 doses
Connecticut	K-12	3 doses TOPV or IPV-3 virus types plus 1 TOPV; or IPV with 2 year boosters
Delaware	K-12	3 doses required
Dist. of Col.	K-12	3 OPV plus booster if series started before 4 years of age
Florida	K-12	4 doses; unless 3rd dose after 4th birthday, then 3 doses
Georgia	K-12	3 doses minimum of TOPV or 4 of IPV given after 1968; last dose must have been given after 4th birthday
Hawaii	K-12	As recommended by American Academy of Pediatrics
Idaho	K-5	3 doses
Illinois	K-12	3 doses; the last a booster on or after 4th birthday
Indiana	K-12	3 doses, oral polio vaccine specified
Iowa	K-12	3 doses, 1 must be after 4 years of age; not required after 18 years of age
Kansas	K-12	3 doses
Kentucky	K-12	3 to 4 doses, the last a booster on or after 4th birthday
Louisiana	New Enterers	4 to 5 doses; at least 1 dose after age 4 years
Maine	K-12	3 doses, 1 of which is given after the 1st birthday
Maryland	K-12	3 dose minimum with 1 after age 4 years
Massachusetts	K-12	3 doses
Michigan	New Enterers	3 doses, not required after 18th birthday
Minnesota	K-12	3 doses
Mississippi	K-12	3 doses, 1 must have been after 4th birthday
Missouri	K-12	3 doses TOPV, at least 1 after age 3 years
Montana	K-12	3 dose minimum o live TOPV, last dose after 4th birthday
Nebraska	K-12	3 doses
Nevada	K-12	3 to 4 doses
New Hampshire	New Enterers	4 doses; 3 if 3rd is on or after 4th birthday
New Jersey	K-12	3 doses OPV including booster; IPV 4 doses including booster 1968 and after
New Mexico	K-12	3 doses, at least 1 dose after 4th birthday
New York	K-12	3 or more doses of TOPV, or 4 or more doses of IPV, and administered after 1968
North Carolina	K-12	4 doses oral vaccine; 3 doses by age 2 yrs; 1 dose on or after 4 years
North Dakota	K-12	4 doses
Ohio	K-12	3 doses OPV or 4 IPV through 17 years of age
Oklahoma	K-12	3 doses
Oregon	K-12	4 doses; 3 for grades 2-12 in Oregon schools on 3/14 82 unless 1 or more received before 6 months, then 4 doses
Pennsylvania	K-12	3 doses OPV or 4 doses IPV
Puerto Rico	K-12	3 doses, provided the 3rd is given after 4th birthday
Rhode Island	K-12	3 doses
South Carolina	K-12	3 doses, at least 1 must be on or after 4th birthday
South Dakota	K-12	3 doses OPV or 4 doses IPV, at least 1 received after the 4th birthday
Tennessee	K-12	4 doses, 1 dose given on or after the 6th birthday
Texas	K-12	3 doses, 1 dose since 4th birthday; through 17 years old
Utah	K-12	3 doses
Vermont	K-12	3 doses, with 6 months between 2nd dose and any thereafter
Virginia	K-12	3 doses, with 3rd after 4th birthday
Washington	K-12	3 doses, last dose must be at or after age 4 years
West Virginia	New Enterers	3 doses minimum, with 1 after 4th birthday, not given after 18 years of age
Wisconsin	K-12	4 doses, only 3 if 3rd received after 4th birthday
Wyoming	New Enterers	4 doses, entering Wyoming schools

Physician Diagnosis of Disease Accepted as Evidence of Immunity (K-12)

■ Accepted ☐ Not Accepted ⊟ Not Applicable (Immunity not required)

State	Diphtheria	Tetanus	Pertussis	Measles	Mumps	Rubella	Polio
Alabama		■			■		
Alaska					⊟		
Arizona		⊟	⊟		⊟		
Arkansas	■	■	■	■	⊟	■	■
California				■			
Colorado				■	■		
Connecticut				■	■		
Delaware							
Dist. of Col.	■	■	■		■		■
Florida				■			
Georgia							
Hawaii				■	■		
Idaho			⊟	■	■		
Illinois				■	■		
Indiana				■	■		
Iowa				■	⊟		
Kansas				■	■	■	
Kentucky			⊟	■	⊟		
Louisiana	■	■	■	■	■	■	■
Maine							
Maryland					⊟		
Massachusetts	■	■	■	■	■		■
Michigan				■		■	
Minnesota				■			
Mississippi				■	⊟	■	
Missouri	■	⊟	⊟	■	⊟	■	■
Montana			⊟	■	⊟		
Nebraska							
Nevada				■	⊟		
New Hampshire				■	■		
New Jersey				■	■		
New Mexico					⊟		
New York		⊟	⊟	■	■		
North Carolina				■			
North Dakota							
Ohio				■	■		
Oklahoma				■	⊟		
Oregon			⊟	■	■	■	
Pennsylvania			⊟		■		
Puerto Rico		■	■	■	■	■	■
Rhode Island			⊟				
South Carolina					⊟		
South Dakota				■			
Tennessee				■	⊟		
Texas			⊟	■	■		
Utah				■	■		
Vermont				■	⊟		
Virginia							
Washington			⊟	■			
West Virginia		■	■	■	⊟		■
Wisconsin							
Wyoming					■		

Immunization Date and Dose Documentation Required (K-12)

■ Single date/dose documentation required ▩ Mixed date/dose documentation used

State	Dose Only	Applicable Vaccines	Dose & Year	Applicable Vaccines	Dose & Mo/Yr	Applicable Vaccines	Dose & M/D/Y	Applicable Vaccines
Alabama					■	ALL		
Alaska							■	ALL
Arizona					▩	D,PO,R	▩	MEASLES
Arkansas							■	ALL
California					■	ALL		
Colorado					▩	DTP,PO	▩	MMR
Connecticut							■	ALL
Delaware					■	ALL		
Dist. of Col.	■	ALL						
Florida							▩	ALL
Georgia					▩	ALL		
Hawaii							▩	ALL
Idaho							■	ALL
Illinois							■	ALL
Indiana					▩	DTP,PO	▩	MMR
Iowa							■	ALL
Kansas							■	ALL
Kentucky					■	ALL		
Louisiana					▩	DTP,PO,MU,R	▩	MEASLES
Maine					■	ALL		
Maryland							▩	ALL
Massachusetts					▩	ALL		
Michigan					▩	DTP,PO	▩	MMR
Minnesota					▩	DTP,PO,MU,R	▩	MEASLES
Mississippi					■	ALL		
Missouri					■	ALL		
Montana					▩	DT,PO,R	▩	MEASLES
Nebraska					■	ALL		
Nevada					■	ALL		
New Hampshire							■	ALL
New Jersey					▩	DTP,PO	▩	MMR
New Mexico							■	ALL
New York			▩	D,PO			▩	MMR
North Carolina							■	ALL
North Dakota					■	ALL		
Ohio							▩	ALL
Oklahoma					■	ALL		
Oregon					■	ALL		
Pennsylvania					■	ALL		
Puerto Rico					■	ALL		
Rhode Island					■	ALL		
South Carolina					▩	DTP,PO	▩	ME,R
South Dakota					■	ALL		
Tennessee					■	ALL		
Texas					■	ALL		
Utah					■	ALL		
Vermont			■	ALL				
Virginia							▩	ALL
Washington					■	ALL		
West Virginia							▩	ALL
Wisconsin							■	ALL
Wyoming							■	ALL

ALL = All vaccines required by individual states

Exemptions from Immunization Requirements (K-12)

■ Allowed ☐ Not Allowed

State	Medical	Religious	Philosophical
Alabama	■	■	
Alaska	■	■	
Arizona	■	■	■
Arkansas	■	■	
California	■	■	■
Colorado	■	■	■
Connecticut	■	■	
Delaware	■	■	■
Dist. of Col.	■	■	
Florida	■	■	
Georgia	■	■	
Hawaii	■	■	
Idaho	■	■	■
Illinois	■	■	
Indiana	■	■	■
Iowa	■	■	
Kansas	■	■	
Kentucky	■	■	
Louisiana	■	■	■
Maine	■	■	■
Maryland	■	■	
Massachusetts	■	■	
Michigan	■	■	■
Minnesota	■	■	■
Mississippi	■		
Missouri	■	■	■
Montana	■	■	■
Nebraska	■	■	■
Nevada	■	■	
New Hampshire	■	■	
New Jersey	■	■	
New Mexico	■	■	
New York	■	■	
North Carolina	■	■	
North Dakota	■	■	■
Ohio	■	■	■
Oklahoma	■	■	■
Oregon	■	■	
Pennsylvania	■	■	■
Puerto Rico	■	■	
Rhode Island	■	■	■
South Carolina	■	■	
South Dakota	■	■	
Tennessee	■	■	
Texas	■	■	
Utah	■	■	■
Vermont	■	■	■
Virginia	■	■	
Washington	■	■	
West Virginia	■		
Wisconsin	■	■	■
Wyoming	■	■	

Immunization Requirements Applicable to Any or All Students Enrolled in K-12, Day-Care, and College

▨ Required ☐ Not Required ⊟ Not Applicable (no law or requirement)

	Diphtheria			Tetanus			Pertussis			Measles			Mumps			Rubella			Polio		
	K-12	Day Care	College	K-12	Day Care	College	K-12	Day Care	College	K-12	Day Care	College	K-12	Day Care	College	K-12	Day Care	College	K-12	Day Care	College
Alabama	▨	▨	⊟	▨	▨	⊟	▨	▨	⊟	▨	▨	⊟	▨	▨	⊟	▨	▨	⊟	▨	▨	⊟
Alaska	▨	▨	⊟	▨	▨	⊟	▨	▨	⊟	▨	▨	⊟	☐	☐	⊟	▨	▨	⊟	▨	▨	⊟
Arizona	▨	☐	⊟	☐	☐	⊟	☐	☐	⊟	▨	☐	⊟	☐	☐	⊟	▨	☐	⊟	▨	☐	⊟
Arkansas	▨	▨	☐	▨	▨	☐	▨	▨	☐	▨	▨	▨	☐	☐	☐	▨	▨	▨	▨	▨	☐
California	▨	▨	⊟	▨	▨	⊟	▨	▨	⊟	▨	▨	⊟	▨	▨	⊟	▨	▨	⊟	▨	▨	⊟
Colorado	▨	▨	⊟	▨	▨	⊟	▨	▨	⊟	▨	▨	⊟	▨	▨	⊟	▨	▨	⊟	▨	▨	⊟
Connecticut	▨	▨	⊟	▨	▨	⊟	▨	▨	⊟	▨	▨	⊟	▨	▨	⊟	▨	▨	⊟	▨	▨	⊟
Delaware	▨	⊟	⊟	▨	⊟	⊟	▨	⊟	⊟	▨	⊟	⊟	▨	⊟	⊟	▨	⊟	⊟	▨	⊟	⊟
Dist. of Col.	▨	▨	▨	▨	▨	▨	☐	☐	☐	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	☐
Florida	▨	▨	☐	▨	▨	☐	▨	▨	☐	▨	▨	▨	▨	▨	☐	▨	▨	▨	▨	▨	☐
Georgia	▨	▨	⊟	▨	▨	⊟	▨	▨	⊟	▨	▨	⊟	▨	▨	⊟	▨	▨	⊟	▨	▨	⊟
Hawaii	▨	▨	⊟	▨	▨	⊟	▨	▨	⊟	▨	▨	⊟	▨	▨	⊟	▨	▨	⊟	▨	▨	⊟
Idaho	▨	⊟	⊟	▨	⊟	⊟	☐	⊟	⊟	▨	⊟	⊟	▨	⊟	⊟	▨	⊟	⊟	▨	⊟	⊟
Illinois	▨	▨	⊟	▨	▨	⊟	▨	▨	⊟	▨	▨	⊟	▨	▨	⊟	▨	▨	⊟	▨	▨	⊟
Indiana	▨	▨	⊟	▨	▨	⊟	▨	▨	⊟	▨	▨	⊟	▨	☐	⊟	▨	▨	⊟	▨	▨	⊟
Iowa	▨	▨	⊟	▨	▨	⊟	▨	▨	⊟	▨	▨	⊟	☐	☐	⊟	▨	▨	⊟	▨	▨	⊟
Kansas	▨	▨	⊟	▨	▨	⊟	▨	▨	⊟	▨	▨	⊟	▨	▨	⊟	▨	▨	⊟	▨	▨	⊟
Kentucky	▨	▨	⊟	▨	▨	⊟	☐	▨	⊟	▨	▨	⊟	☐	☐	⊟	▨	▨	⊟	▨	▨	⊟
Louisiana	▨	▨	⊟	▨	▨	⊟	▨	▨	⊟	▨	▨	⊟	▨	▨	⊟	▨	▨	⊟	▨	▨	⊟
Maine	▨	▨	▨	▨	▨	▨	▨	▨	☐	▨	▨	▨	▨	▨	☐	▨	▨	▨	▨	▨	☐
Maryland	▨	▨	⊟	▨	▨	⊟	▨	▨	⊟	▨	▨	⊟	☐	☐	⊟	▨	▨	⊟	▨	▨	⊟
Massachusetts	▨	▨	▨	▨	▨	▨	▨	▨	☐	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	▨	☐
Michigan	▨	▨	⊟	▨	▨	⊟	▨	▨	⊟	▨	▨	⊟	▨	▨	⊟	▨	▨	⊟	▨	▨	⊟
Minnesota	▨	▨	⊟	▨	▨	⊟	▨	▨	⊟	▨	▨	⊟	▨	▨	⊟	▨	▨	⊟	▨	▨	⊟
Mississippi	▨	▨	☐	▨	▨	☐	▨	▨	☐	▨	▨	▨	☐	▨	☐	▨	▨	▨	▨	▨	☐
Missouri	▨	⊟	⊟	☐	⊟	⊟	☐	⊟	⊟	▨	⊟	⊟	☐	⊟	⊟	▨	⊟	⊟	▨	⊟	⊟
Montana	▨	▨	⊟	▨	☐	⊟	☐	▨	⊟	▨	▨	⊟	☐	☐	⊟	▨	▨	⊟	▨	▨	⊟
Nebraska	▨	▨	⊟	▨	▨	⊟	☐	☐	⊟	▨	▨	⊟	▨	▨	⊟	▨	▨	⊟	☐	☐	⊟
Nevada	▨	▨	⊟	▨	▨	⊟	☐	☐	⊟	▨	▨	⊟	☐	☐	⊟	▨	▨	⊟	☐	☐	⊟
New Hampshire	☐	☐	⊟	☐	☐	⊟	☐	☐	⊟	☐	☐	⊟	☐	☐	⊟	▨	☐	⊟	☐	☐	⊟
New Jersey	☐	☐	⊟	▨	☐	⊟	☐	☐	⊟	☐	☐	⊟	☐	☐	⊟	▨	☐	⊟	☐	☐	⊟
New Mexico	☐	☐	⊟	☐	☐	⊟	☐	☐	⊟	☐	☐	⊟	☐	☐	⊟	▨	☐	⊟	☐	☐	⊟
New York	☐	☐	⊟	☐	☐	⊟	☐	☐	⊟	☐	☐	⊟	☐	☐	⊟	▨	☐	⊟	☐	☐	⊟
North Carolina	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
North Dakota	▨	▨	⊟	▨	☐	⊟	☐	☐	⊟	☐	☐	⊟	☐	☐	⊟	▨	▨	⊟	☐	☐	⊟
Ohio	▨	▨	⊟	▨	☐	⊟	☐	☐	⊟	☐	☐	⊟	☐	☐	⊟	▨	▨	⊟	☐	☐	⊟
Oklahoma	☐	☐	⊟	☐	☐	⊟	☐	☐	⊟	☐	☐	⊟	☐	☐	⊟	☐	☐	⊟	☐	☐	⊟
Oregon	☐	☐	⊟	☐	☐	⊟	☐	☐	⊟	☐	☐	⊟	☐	☐	⊟	☐	☐	⊟	☐	☐	⊟
Pennsylvania	☐	☐	⊟	☐	☐	⊟	☐	☐	⊟	☐	☐	⊟	☐	☐	⊟	☐	☐	⊟	☐	☐	⊟
Puerto Rico	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Rhode Island	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
South Carolina	☐	☐	⊟	☐	☐	⊟	☐	☐	⊟	☐	☐	⊟	☐	☐	⊟	☐	☐	⊟	☐	☐	⊟
South Dakota	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Tennessee	☐	☐	⊟	☐	☐	⊟	☐	☐	⊟	☐	☐	⊟	☐	☐	⊟	☐	☐	⊟	☐	☐	⊟
Texas	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Utah	☐	☐	⊟	☐	☐	⊟	☐	☐	⊟	☐	☐	⊟	☐	☐	⊟	☐	☐	⊟	☐	☐	⊟
Vermont	☐	☐	⊟	☐	☐	⊟	☐	☐	⊟	☐	☐	⊟	☐	☐	⊟	☐	☐	⊟	☐	☐	⊟
Virginia	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Washington	☐	☐	⊟	☐	☐	⊟	☐	☐	⊟	☐	☐	⊟	☐	☐	⊟	☐	☐	⊟	☐	☐	⊟
West Virginia	▨	▨	⊟	▨	☐	⊟	☐	☐	⊟	☐	☐	⊟	☐	☐	⊟	▨	▨	⊟	☐	☐	⊟
Wisconsin	▨	▨	⊟	▨	▨	⊟	☐	☐	⊟	☐	☐	⊟	☐	☐	⊟	▨	▨	⊟	☐	☐	⊟

Enforcement of Immunization Requirements

▩ Law/requirement contains clause ☐ Law/requirement does not contain clause
⊟ Not Applicable (No law or requirement)

State	Penalty Clause for Noncompliance			Exclusion Clause for Noncompliance		
	K-12	Day-Care	College	K-12	Day-Care	College
Alabama	▩	▩	⊟	▩	☐	⊟
Alaska	☐	☐	⊟	▩	▩	⊟
Arizona	☐	☐	⊟	▩	▩	⊟
Arkansas	▩	▩	☐	▩	☐	☐
California	☐	☐	⊟	▩	▩	⊟
Colorado	☐	☐	⊟	▩	▩	⊟
Connecticut	▩	▩	⊟	☐	☐	⊟
Delaware	☐	⊟	⊟	▩	⊟	⊟
Dist. of Col.	☐	▩	☐	▩	▩	☐
Florida	☐	☐	☐	▩	▩	▩
Georgia	▩	▩	⊟	▩	▩	⊟
Hawaii	▩	▩	⊟	▩	▩	⊟
Idaho	☐	⊟	⊟	☐	⊟	⊟
Illinois	▩	▩	⊟	▩	☐	⊟
Indiana	☐	☐	⊟	▩	☐	⊟
Iowa	▩	▩	⊟	☐	☐	⊟
Kansas	☐	▩	⊟	▩	☐	⊟
Kentucky	▩	▩	⊟	▩	☐	⊟
Louisiana	▩	▩	⊟	▩	▩	⊟
Maine	☐	☐	☐	▩	▩	▩
Maryland	☐	☐	⊟	▩	▩	⊟
Massachusetts	☐	▩	☐	▩	▩	☐
Michigan	▩	▩	⊟	▩	▩	⊟
Minnesota	☐	☐	⊟	▩	▩	⊟
Mississippi	▩	▩	☐	▩	▩	▩
Missouri	☐	⊟	⊟	▩	⊟	⊟
Montana	▩	☐	⊟	▩	▩	⊟
Nebraska	▩	▩	⊟	▩	▩	⊟
Nevada	▩	▩	⊟	▩	▩	⊟
New Hampshire	☐	▩	⊟	▩	▩	⊟
New Jersey	▩	▩	⊟	▩	▩	⊟
New Mexico	▩	▩	⊟	▩	▩	⊟
New York	▩	☐	⊟	▩	▩	⊟
North Carolina	▩	☐	☐	▩	▩	☐
North Dakota	▩	▩	⊟	▩	▩	⊟
Ohio	☐	☐	⊟	▩	▩	⊟
Oklahoma	▩	▩	⊟	▩	▩	⊟
Oregon	☐	☐	⊟	▩	▩	⊟
Pennsylvania	▩	▩	⊟	▩	☐	⊟
Puerto Rico	▩	▩	☐	▩	▩	▩
Rhode Island	☐	☐	☐	▩	▩	▩
South Carolina	▩	▩	⊟	▩	▩	⊟
South Dakota	☐	▩	☐	▩	☐	☐
Tennessee	▩	▩	⊟	☐	☐	⊟
Texas	☐	☐	☐	☐	☐	☐
Utah	▩	☐	⊟	▩	▩	⊟
Vermont	☐	☐	⊟	▩	☐	⊟
Virginia	▩	☐	☐	☐	▩	☐
Washington	☐	☐	⊟	▩	▩	⊟
West Virginia	▩	☐	⊟	☐	☐	⊟
Wisconsin	▩	☐	⊟	▩	▩	⊟
Wyoming	☐	☐	☐	▩	▩	▩

Rubella Susceptibility Testing

■ Required ☐ Not Required

State	Premarital	Hospital Employee
Alabama		
Alaska		■
Arizona		
Arkansas		
California	■	
Colorado	■	
Connecticut	■	
Delaware		
Dist. of Col.		
Florida		
Georgia	■	
Hawaii	■	
Idaho	■	
Illinois		
Indiana	■	
Iowa		
Kansas		
Kentucky		
Louisiana		
Maine		■
Maryland		■
Massachusetts		
Michigan		
Minnesota		
Mississippi		
Missouri		
Montana	■	
Nebraska	■	
Nevada		
New Hampshire		■
New Jersey		
New Mexico	■	
New York	■	■
North Carolina		
North Dakota		
Ohio		
Oklahoma		
Oregon		
Pennsylvania		
Puerto Rico		
Rhode Island	■	■
South Carolina		
South Dakota		
Tennessee		
Texas		
Utah		
Vermont		
Virginia		
Washington		
West Virginia		
Wisconsin		
Wyoming	■	

Immunization of Rubella Susceptibles

■ Required ☐ Not Required

State	Premarital	Hospital Employee
Alabama		
Alaska		■
Arizona		
Arkansas		
California		
Colorado		
Connecticut	■	
Delaware		
Dist. of Col.		
Florida		
Georgia		
Hawaii		
Idaho		
Illinois		
Indiana		
Iowa		
Kansas		
Kentucky		
Louisiana		
Maine		■
Maryland		
Massachusetts		
Michigan		
Minnesota		
Mississippi		
Missouri		
Montana		
Nebraska		
Nevada		
New Hampshire		■
New Jersey		
New Mexico		
New York		■
North Carolina		
North Dakota		
Ohio		
Oklahoma		
Oregon		
Pennsylvania		
Puerto Rico		
Rhode Island		■
South Carolina		
South Dakota		
Tennessee		
Texas		
Utah		
Vermont		
Virginia		
Washington		
West Virginia		
Wisconsin		
Wyoming		

Alaska State Legislature
House of Representatives
COMMITTEE ON HEALTH, EDUCATION
AND SOCIAL SERVICES

OFFICIAL BUSINESS

POUCH V
JUNEAU, AK 99811
465-3759

March 8, 1988

Honorable Ted Stevens
United State Senate
522 Hart Building
Washington, D.C. 20510

Dear Senator Stevens:

As the Co-Chairs of the Alaska House Health, Education, and Social Services Committee, we would like to recommend Shannon Kohler be appointed to the federal Commission being created in conjunction with the National Childhood Vaccine Injury Compensation Act.

Ms Kohler has a strong viewpoint on the subject of mandatory immunization and has put considerable effort into researching and organizing around it. We believe the federal Commission to be an appropriate place for someone with her concerns to serve. She would undoubtedly make a hard working member of such a commission.

It is our understanding that Shannon is also being recommended by the Alaska Department of Health and Social Services, by the Senate HESS Chair, Senator Paul Fischer, and by Representative Mike Navarre.

Thank you for your attention to this matter. We will continue to monitor discussions around the subjects of immunization and public health.

Sincerely,

Rep. Niilo Koponen, Co-Chair

Rep. Johnny Ellis, Co-Chair

CC: Shannon Kohler
NK/JE/ljm

POSITION PAPER/Department of Health & Social Services

Position Paper

HB 277

For an Act entitled: "An Act relating to the immunization of minors."

HB 277 proposes the following changes in statutes pertaining to the immunization of minors in Alaska:

1. Section 1 amends AS 14.30.125 by removing the requirements for immunization against specific diseases as a condition for admission to schools, preschools, nurseries, or day care or child care when a parent or legal guardian states that immunization is contrary to the parent's or guardian's philosophical beliefs. (The Alaska Administrative Code currently exempts children whose parents object to immunizations because of religious beliefs.)

2. Section 2 requires that an individual or facility administering vaccine must provide the following information to the parent or guardian prior to the immunization: (a) a written explanation of the risks and benefits associated with the immunization; (b) a copy of the product insert required by the Food and Drug Administration; (c) a list of symptoms of adverse reactions to the immunization; and (d) a copy of the pertinent legislation and regulations. Moreover, the person who administers the immunization must ascertain that the parent or guardian has received and understands the materials provided.

3. Proposed Section AS 18.15.310 requires that health care providers submit and the Department of Health and Social Services investigate any reports of adverse reactions to immunizations and requires the department to report annually to the legislature on the incidence of infectious disease and the incidence of serious reactions and permanent or long-term damage to minors that results from immunization.

4. Proposed Section AS 18.15.320 requires that records of lot numbers and vaccine manufacturers be maintained for three years after immunization.

The first three of these provisions are discussed below.

1. <u>Exemption from mandatory immunization requirements based on philosophical beliefs of parent or guardian</u>

AS 14.30.125 authorizes the Department of Health and Social Services to require that children entering school be immunized against diseases

specified by the commissioner. Currently, regulations (7 AAC 50.255) require immunizations against diphtheria, tetanus, polio, measles, rubella, and if the child is under seven years of age, pertussis. Regulations allow a child to be exempted from immunization requirements if receiving the immunization is contrary to the religious beliefs of the parent or guardian or if there are medical reasons to exempt the child. 7 AAC 50.255, adopted under the authority of AS 47.35.030, requires that a child receive immunizations "appropriate to his age as prescribed in the Alaska Division of Public Health's schedule for active immunization" as a condition of admission to day care.

Although "childhood diseases" are commonly thought to be benign, complications do occur and can be severe. For example, inflammation of the heart muscle can complicate diphtheria; pneumonia is one of the chief complications of both measles and pertussis; and neurological damage can occur with diphtheria, measles, mumps, and pertussis. Rubella can cause a wide spectrum of congenital disorders when acquired by the mother during pregnancy. The goal of rubella immunization programs is to assure immunity of all females before they reach childbearing age and to limit the accidental exposure of pregnant women to the virus.

Vigorous immunization efforts aimed particularly at very young children have virtually eliminated most of the vaccine-preventable diseases, as seen in the following table:

	Diphtheria	Measles	Mumps	Pertussis	Rubella
1976	8	14	39	0	2
1977	2	60	35	5	1
1978	3	1	15	18	8
1979	0	17	15	10	4
1980	0	6	15	5	12
1981	1	0	20	1	1
1982	0	1	6	0	1
1983	0	1	10	0	0
1984	0	0	8	3	1
1985	0	0	10	30	1
1986	0	0	8	5	0

Unfortunately, vaccines are not perfect. Vaccines are not 100 per cent effective, and therefore some people who are immunized may not be protected. Also, vaccines are not perfectly safe, and some people who receive them may be damaged by them. The question is one of balancing the benefits to the individual receiving the vaccine and the benefits to society in general against the risk of damage.

In recent years, debate on benefit v. risk has centered on the pertussis vaccine. (Pertussis is a component of the DPT vaccine, one of the "baby shots.") Reactions to the vaccine are relatively common since about 40 per cent of vaccinated children develop minor redness, swelling, and pain at the site of injection. Fever, vomiting, and drowsiness occur in about 20 per cent of vaccines. Convulsions or collapse with complete recovery occur at a rate of about one episode per 1,750 vaccine doses given. Encephalitis occurs at a rate of one case per 110,000 doses

given, and encephalitis with residual defect at a rate of one case per 310,000 doses administered. Sudden infant death syndrome is not related to pertussis vaccine use.

Given the relatively low incidence of pertussis, the adverse effects associated with the vaccine seem prominent. However, for perspective, the effects of the disease itself should be considered. The death rate from pertussis for previously unvaccinated patients who develop the disease is one in 1,000; among affected children less than one year of age, the death rate is one per cent. Permanent brain damage from whooping cough afflicts one child in 10,000 cases. Consensus among health authorities is that the benefit from immunization outweighs the risk. This view has been expressed by the American Medical Association, the Public Health Service, the American Academy of Pediatrics, and the American Public Health Association.

The department believes that because the proposed exemption includes individuals with philosophical objections to immunization, a serious health threat for many Alaskan children will be created. There will be increased risk for those whose parents or guardians elect to exclude them from immunization. There will be increased risk to very young children in other families who have not had a chance to complete the entire series of injections. There will be increased risk to the 10 to 20 per cent of completely immunized children who are incompletely protected because the vaccine is not 100 per cent effective. The decision not to immunize has effects that extend beyond the individual.

Since the decision not to immunize is likely to be unevenly distributed across the population, it is thought that there will be geographic areas in which significant numbers of children will be unimmunized and where the likelihood of disease occurrence will be great.

The recent upswing in reported cases of pertussis in Alaska is directly attributable to the nonimmunized or inadequately immunized status of the cases.

2. Immunization Information

Much of the intent of this portion of the proposed bill is already required by the department as a part of its agreement with the federal Centers for Disease Control, through whom the state's vaccine supply is purchased. The department provides the major portion of vaccines used in the state, with the exception of vaccines used by the military. A written explanation of risks and benefits called the Important Information Statement is used in the public sector. By signing the statement, the parent or guardian states that he or she has read the statement and has had an opportunity to ask questions of the person administering the vaccine. The manufacturer's name and vaccine lot number are recorded and retained. Private physicians who receive vaccine from the state can use the Important Information Statement system or exercise their professional judgement in informing parents or guardians of the risks and benefits of immunization. Written descriptions of potential adverse reactions are also provided. Copies of applicable statutes and regulations are not distributed or discussed.